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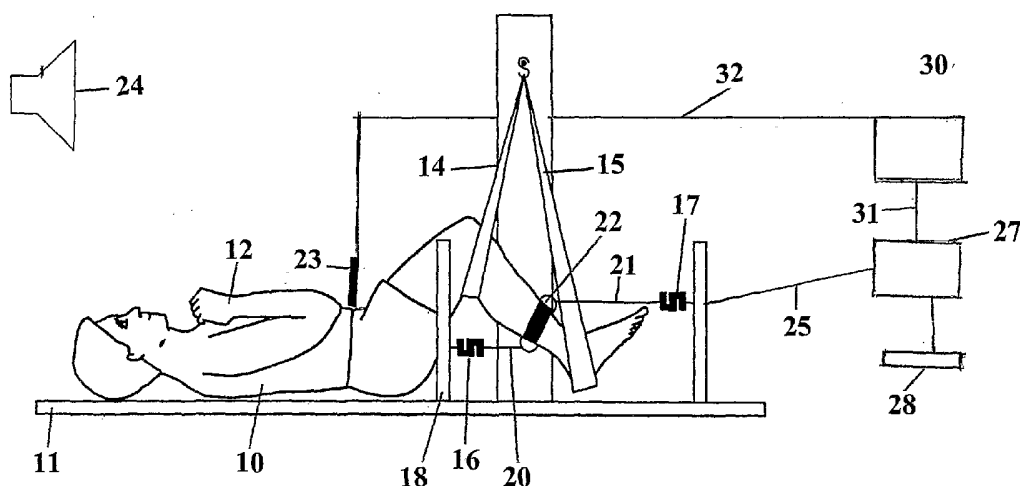
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(54) Title: **MUSCLE ASSESSMENT**



(57) Abstract: A method and device for assessing the function of deep muscle of a subject. The method comprising the steps of: monitoring at least one characteristic of the deep muscle while the subject performs either a first activity and a second activity each of which cause contraction of the deep muscle and which generate respective forces in a different direction to each other or an activity that initiates involuntary activation of the deep muscle; and analysing results of the monitoring to provide an indication of the function of the deep muscle. It is preferred that characteristic is the width of the muscle. The device comprises a patient table (11), force transducers (16,17) and an ultrasound device (30) for visualising the deep muscle of interest. The device may also incorporate a computer (27) connected to the transducers and ultrasound device. The computer may be programmed to provide cues to the subject during conduct of an assessment session and to analyse information obtained from the session. The device may also include one or more slings (14,15) for supporting a limb of the subject.

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TITLE

“MUSCLE ASSESSMENT”

FIELD OF THE INVENTION

THIS INVENTION relates to a method and device for assessing the
5 function of deep muscles. More particularly, the invention relates to a method and device
for assessing the function of the deep muscles that are important for the control of joint
motion and stability. The assessment of the function of the deep muscle may provide an
indication of the propensity for, or severity of, musculoskeletal pain in a subject. The
invention is particularly directed at deep muscles of the trunk but should not be seen as
10 limited to these anatomical features.

BACKGROUND OF THE INVENTION

Motor control of the trunk muscles has been studied extensively in people
with and without low back and pelvic pain (LBP). Numerous changes in muscle
recruitment have been identified in the LBP population including increased activity of the
15 erector spinae (ES) muscles during trunk movements,¹ delayed relaxation in response to
unloading² and reduced activity during functional movements.³ Publications referred to in
this specification are collected and identified at the end of this text.

Although, many studies report high variability between individuals,²
changes in recruitment of the deep intrinsic muscles have been reported to be a consistent
20 finding. For instance, the onset of activity of the deep abdominal muscle, transversus
abdominis (TrA), has been reported to be delayed in association with rapid limb movement
in people with recurrent episodes of low back pain.⁴⁻⁷ Furthermore, morphological changes
have been identified in the deep paraspinal muscles, which provide indirect evidence for
changes in recruitment.⁸⁻⁹ In conjunction with these findings, clinical rehabilitation
25 strategies have been developed to retrain the control and coordination of the trunk muscles,
particularly the deep muscles.¹⁰ Although, there is evidence of efficacy of these approaches
from clinical trials,¹¹⁻¹⁶ the clinical evaluation of the coordination of the deep intrinsic
spinal muscles is problematic.

Due to the depth of the intrinsic spinal muscles and the proximity of
30 adjacent muscles, clinical assessment of activity is difficult. Attempts have been made to
develop clinical tests based on palpation of the muscle activity¹⁷ and measurement of

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movement of the abdominal wall with a pressure cuff placed under the abdomen and the subject positioned prone.¹⁰ While there is preliminary evidence that the latter test is related to the pattern of recruitment of the abdominal muscles,¹⁸ at best it can provide an indirect measure of trunk muscle recruitment. More recent attempts have focussed on the use of
5 ultrasound imaging of muscle.¹⁹ Ultrasound measurement of the cross-sectional area of multifidus has been shown to be valid²⁰ and is reduced in people with acute unilateral LBP.¹² However, it has not been established whether ultrasound measurement can provide a meaningful measure of motor control.

It would be of great assistance to provide a non-invasive method for
10 assessing the function of deep musculature in general and, in particular, the transversus abdominis.

SUMMARY OF THE INVENTION

Throughout this specification, unless the context requires otherwise, the word “comprise”, or variations such as “comprises” or “comprising”, will be understood to
15 imply the inclusion of a stated element or integer or group of elements or integers but not the exclusion of any other element or integer or group of elements or integers.

In one form although it need not be the only or indeed the broadest form, the invention resides in a method for assessing function of a deep muscle of a subject, the method comprising the steps of:

20 monitoring at least one characteristic of the deep muscle while the subject uses an anatomical structure to perform a first activity and a second activity, each of which cause contraction of the deep muscle in at least some subjects, wherein the first activity and second activity generate respective first and second forces each in a direction different to the other; and

25 analysing results of the monitoring of the at least one characteristic to provide an indication of the function of the deep muscle.

The method may further comprise monitoring the at least one characteristic of deep muscle at rest and determining changes from rest to the activities.

The preferred deep muscle may be the one of the trunk muscles. Preferably
30 the deep muscle is the transversus abdominis (TrA). The deep muscle may be the multifidus, the deep cervical flexors and/or the paraspinal muscles. The term “deep

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muscle” in the specification should be understood to extend to two or more muscles or muscle groups.

Monitoring at least one characteristic of the muscle may include using one or more of ultrasound imaging, electromyographic techniques and other suitable means for
5 assessing change in the deep muscle. Preferably, monitoring includes the step of recording information on the at least one characteristic and any change that may occur.

The at least one characteristic may include one or more of the thickness of the muscle, length of the muscle and electrical activity of the muscle.

The anatomical structure is preferably one or more limbs of the subject.

10 The first activity and second activity may include movement of the anatomical structure. Preferably the first activity and second activity are isometric exercises or actions. The first activity may be one of extension, flexion and rotation or an attempt to do so. The second activity may be one of extension, flexion and rotation or an attempt to do so. Multiple different actions may be used in each activity. The method is
15 not necessarily limited to two activities and three or four may be used, each with a different direction of force. The activities preferably start from the same position of the anatomical structure.

The directions of the first and second forces are preferably separated or divergent by at least 15°. Most preferably the directions are separated by 25° or more.
20 The directions of the first and second forces may be opposed. Therefore, the directions of the forces may be between 15° and 345°. The forces may be generated by attempts to rotate the anatomical structure, preferably in opposite directions.

Analysing the results of monitoring at least one characteristic may include comparing a change between at least one characteristic during the first activity and at least
25 one characteristic during the second activity. Comparison of the changes may include subtraction, division, addition, averaging, expressing as a percentage or other comparative or analytical process. Analysing the results may include the step of comparing the at least one characteristic during the activities with a baseline resting value for the deep muscle. Analysing the results of monitoring the at least one characteristic may include comparing
30 the results of the subject against a reference database. The reference database may be formed from measurements taken from a plurality of different subjects, preferably subjects

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with deep muscle function considered to be in a normal range. Analysing results of monitoring the at least one characteristic may include submitting results to processing means programmed to provide an indication of the function of the deep muscle.

The method may further comprise the step of minimising the effect of gravity by supporting the anatomical structure and, in particular, one or more limbs. Preferably, the method involves supporting at least one limb clear of any surface and without the need for the subject to exert any muscular force to maintain its resting position. If the limb is a leg, preferably the leg is supported at or around the level of the knee and at or around the level of the ankle.

10 The method may involve the use of one or more force transducers to assess the power of muscle activity. Of course, any suitable arrangement for indicating force may be used and may be analogue or digital. The force transducers or other arrangement may be aligned along a direction of action of the first and second forces.

Monitoring at least one characteristic of the deep muscle preferably involves the use of ultrasonography to provide a visual image of the muscle during activity.

Most preferably the method includes the step of directing the subject to exert a predetermined force. Preferably the force lies within the range of between 1% and 30% of maximal voluntary contraction (MVC) of the anatomical structure. Most preferably the force lies in the range of 5-20% of MVC. Particularly preferred levels of force are 7.5% and 15% of MVC.

The method may further involve monitoring at least one characteristic of the deep muscle at two or more different preselected forces.

25 The preselected force may be selected as a percentage of body weight or a standardised mass or a percentage of the subjects maximal voluntary contraction. The percentage of body weight is preferably in the range of 1% to 30%. Most preferably the percentage of body weight is in the range of 5-20%. The percentage of body weight may be 7.5% and 15%.

30 In a second broad aspect, the invention resides in a method of assessing the function of a deep muscle of a subject, the method comprising the steps of monitoring at least one characteristic of the deep muscle while the subject performs an activity that

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initiates or may initiate substantially involuntary activation of the deep muscle. Preferably the deep muscle is one of the trunk muscles and most preferably the TrA.

The involuntary activation of the muscle is preferably initiated during a first activity of an anatomical structure such as a limb or limbs creating a force in a first direction and a second activity of the anatomical structure such as a limb or limbs creating a force in a second direction wherein the first direction and the second direction are separated or divergent. The forces may be rotational. Preferably the first and second direction are separated by at least 15°. The first and second direction may be opposed. The activities are preferably isometric, but may be dynamic.

Monitoring the at least one characteristic of the deep muscle may include the step of visualising the deep muscle with an ultrasound device and measuring changes in at least one physical parameter such as the length of the muscle or preferably the width of the muscle. The width of the muscle may be measured around a mid point of the muscle.

Changes in the at least one parameter of the muscle when compared to a resting baseline for the deep muscle, may be compared during the first activity and the second activity. Alternatively, the combined change in the muscle during the first activity and the second activity may be compared to a range provided by assessment of a plurality of subjects. Preferably the plurality of subjects have activity of the deep muscle within a normal range.

Preferably the method further includes the step of minimising or neutralising the effects of gravity during the first activity and second activity. Neutralising or minimising the effect of gravity may include the step of suspending a limb or limbs with a support device.

The method may further include the step of using the indication of muscle function to assess a tendency of the subject to suffer from musculoskeletal pain such as lower back and/or pelvic pain or the severity thereof.

In a further aspect, the invention may reside in a method of assessing a therapeutic or rehabilitation regime for a subject, the method comprising the steps of:

determining a base line assessment of the function of a deep muscle of the subject according to the above method;

instituting a treatment regime in the subject; and

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repeating the assessment of the function of the deep muscle of the subject according to the above method on one or more additional occasions; and

comparing the function of the deep muscle as determined on the one or more additional occasions with the function of the deep muscle at the base line assessment.

5 The regime of treatment may include one or more of exercises, pharmaceutical agents, surgery and physical therapy.

In an alternative aspect, the invention resides in a device for use in assessing the function of a deep muscle of a subject, the device comprising patient support means, force detection means for determining force applied by the subject during an
10 assessment period and, optionally, limb support means. The patient support means may be a table.

The force detection means may comprise one or more force transducers or other form of strain gauges either analogue or digital. The strain gauges may be mechanical or electronic. Each force transducer may be located intermediate attachment
15 means for attaching the force transducer to the limb or limbs and anchoring means for anchoring the force transducer and attachment means. The attachment means may comprise a cord or belt or shackle. The anchoring means may comprise a cord and post.

The assessment period may include a period of muscular activity in the limb or limbs. Preferably the period of muscular activity may include a first activity providing a
20 force in the first direction and a second activity providing a force in a second direction wherein the first direction and the second direction are different. The distance between the first direction and the second direction may be 15° or more. Preferably the difference is 30° or more, most preferably the difference is 45° or more. The first and second directions may be opposed. The force transducers or strain gauges may be arranged in spaced array
25 around the lap. The device may further comprise muscle characteristic monitoring means which may be an US device or EMG device. The device may be adapted to support a limb or limbs of a subject and thereby substantially reduce or minimise the effect of gravity on the limb. The device may include one or more slings to support the limb or limbs. The slings may be anchored to a support structure such as a post.

30 The device may include processing means to analyse the results of monitoring at least one characteristic of the muscle. The processing means may be a

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computer which may be in signal connection with the force transducers and/or the muscle characteristic monitoring means. The computer may be programmed to control a cycle of testing including providing a subject with directions as to duration and intensity of effort.

In yet a further aspect, the invention may reside in a computer programme product allowing a subject to undergo assessment of the function of deep trunk muscle or other muscle and/or tendency to musculoskeletal pain, such as LBP, the computer programme product including computer executable code which, when executed on a suitable processing system, causes the processing system to perform an analysis of the results of monitoring at least one characteristic of a deep muscle when assessed according to the above method.

The computer may be programmed to analyse the data according to one or more of the following:

$$f_1 = \frac{Wa_1 - Wr}{Wr}$$

$$f_2 = \frac{Wa_2 - Wr}{Wr}$$

$$f_3 = f_1 - f_2$$

where

f_1 = a first indicator of function;

Wa_1 = width of the muscle during the first activity;

Wr = width of the muscle at rest;

f_2 = a second indicator of function;

Wa_2 = width of the muscle during the second activity;

f_3 = a third indicator of function.

If f_1 and/or $f_2 < fn_1$, where fn_1 is a lower limit for a normal subject, the muscle function may be impaired.

If $f_3 > fn_2$, where fn_2 is an upper limit for a normal subject, the muscle function may be impaired.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 shows one embodiment of a device of the present invention with a subject in position. The mass of the leg is supported in slings. Subjects isometrically flex

and extend the knee with auditory feedback of force level.

FIG. 2 shows results of ultrasound measurement of muscle activity. Ultrasound images and line drawings of the images are shown for relaxed (upper panel) and contracted (lower panel) conditions for a trial of knee flexion to 15% of body weight in a representative subject. The location of the measurements is indicated in the right panels by the dashed lines and the thickness measurements for the middle of the image are indicated by the arrows.

FIG. 3 shows results of EMG measurement of muscle activity. Raw EMG data are shown for a representative subject for knee flexion to 15% of body weight. The solid line indicates the time at which the ultrasound image was frozen for “relaxed” measurement and the dashed line indicates the time of the “contracted” measurement.

FIG. 4 shows change in thickness and EMG activity for a 7.5% body weight contraction. Mean and SEM group data are shown for the change in muscle thickness (a) and EMG activity (b) averaged over the flexion and extension tasks for control (open circles) and LBP (closed circles) subjects. There was a greater increase in thickness and EMG activity of TrA for the control subjects compared to the subjects with LBP. $*=p<0.05$.

FIG. 5 shows ultrasound data for individual subjects. Individual data for the change in thickness of the abdominal muscles measured with ultrasound imaging for trials in which subjects targeted 7.5% (upper panels) and 15% (lower panels) of body weight for control (open circles) and LBP (closed circles) subjects. Data are shown separately for flexion and extension of the knee. Note that for TrA, control subjects had a greater increase in thickness. In general there was a difference in the increase between the directions of leg task.

FIG. 6 shows change in thickness and EMG activity for the 15% body weight contraction. Mean and SEM group data are shown for the change in muscle thickness (a) and EMG activity (b) averaged over the flexion and extension tasks for control (open circles) and LBP (closed circles) subjects. There was a greater increase in thickness of TrA for the control subjects compared to the subjects with LBP. $*=p<0.05$.

FIG. 7 shows changes to TrA thickness in sedentary and elite individuals.

FIG. 8 shows changes in RA between sedentary and individual elite.

FIG. 9 shows EMG changes in OE between sedentary and elite individuals.

FIG. 10 shows EMB changes in OI between sedentary and elite individuals.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Changes in muscle shape and geometry (e.g. muscle fibre length and pennation angle) have been shown to change with muscle contraction²¹⁻²³ Recent studies indicate that there is a curvilinear relationship between contraction level and changes in these parameters for limb and trunk muscles.²¹⁻²⁴ It has been found that for contractions below ~30% of a maximal voluntary contraction (MVC) this relationship approximates linear. Importantly, there is a linear relationship between changes in muscle thickness of TrA and obliquus internus abdominis (OI) and contraction level, up to 30% MVC. Thus, measurement of changes in muscle thickness of these muscles may be used to provide a viable clinical measure of deep trunk muscle function.

A further consideration is the type of task performed. Previous studies have focussed on voluntary activation of the deep abdominal muscles.^{10 17 25} However, voluntary activation is affected by factors such as motivation and skill learning, which are known to affect outcome of strength and endurance measures.²⁶ Assessment involving measurement of activity in an automatic task can provide additional and more reliable information. The present inventor has developed a test based on evidence of normal control of TrA. Abdominal muscles are recruited during movement of the limbs and this activity is dependent on the amplitude of the reactive forces from limb movement. This trunk muscle response forms part of the associated postural activity to control the trunk. Moreover, the threshold for this activity is increased in people with a history of LBP. Unlike the superficial abdominal muscles, TrA is active in a manner that is not specific to the direction of limb movement. However, this response is direction-specific in people with a history of LBP. Changes in muscles thickness of TrA were measured with both flexion and extension of the legs in people with no history of LBP and people with LBP. The latter showed either no recruitment, decreased recruitment or recruitment with only one direction of movement.

Although the description and examples are directed to the TrA, it should be noted that the present technique is applicable to any muscle wherein relative dysfunction of muscular activity in two divergent directions can provide an indication of a tendency to

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musculoskeletal pain. The general process of the invention may be applied to many joints, in particular but not exclusively, the shoulder, the hip and joints of the neck. Other muscles of the trunk that may be suitable for this technique include the multifidus. In the neck, the deep cervical flexors and paraspinal muscles may also be suitable targets.

5 Likewise, while the description is directed to LBP, it should be understood that other forms of musculoskeletal pain may be a suitable subject of this technique.

EXAMPLE 1

Twenty subjects (10 with a history of LBP and 10 controls) volunteered for assessment. Subjects in the control group had a mean (SD) age, height and weight of 32.7 (10.6) years, 159.5 (37.8) cm, and 68.2 (12.6) kg, respectively. Subjects were excluded

10 from this group if they had a history of LBP that had restricted function or caused them to have time off work, if they had any respiratory or neurological disorder, musculoskeletal pain elsewhere in the spine or lower limbs or if they had been pregnant in the previous 2 years. Subjects in the LBP group had a mean age, height and weight of 27.8 (5.1) years,

15 171.5 (10.3) cm and 68.6 (13.1) kg, respectively. There was no difference between groups in any of these parameters when compared by t-tests (age - $P=0.21$; height - $P=0.35$; weight - $P=.95$). Subjects were included in the LBP group if they had a history of at least one episode of LBP that had limited functional activities (work, sports) in the past 18 months and had an episode of LBP within the past 6 months. Subjects were tested when

20 they were in remission from their symptoms. Subjects were excluded from the LBP group if they had any respiratory or neurological disorder, musculoskeletal pain elsewhere in the spine or lower limbs or if they had been pregnant in the previous 2 years.

Ultrasound images were made with a 5.5 cm 5MHz curved array transducer (Synergy, GE-Diasonics, USA). The transducer was placed in a dense foam cube to

25 minimise changes in angulation or pressure and was placed transversely across the abdominal wall along a line mid-way between the inferior angle of the rib cage and the iliac crest. The medial edge of the transducer was placed approximately 10 cm from the midline. However, the position was adjusted to ensure that the medial edge of TrA was approximately 2 cm from the medial edge of the ultrasound image when the subject was

30 relaxed. The location of the transducer was marked so that identical placement would be used for all measurements. Images were frozen and stored for later analysis. A trigger

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was used to mark, on the EMG record, the time that the images were taken.

Electromyography (EMG) recordings were made using intramuscular fine-wire electrodes fabricated from two strands of Teflon-coated stainless-steel wire (75 μ m diameter, A-M systems, USA) threaded into a hypodermic needle (0.6x32 mm) and
5 inserted under the guidance of ultrasound imaging into the right ventro-lateral abdominal wall muscles; TrA, obliquus internus abdominis (OI), and obliquus externus abdominis (OE). Electrodes were inserted mid-way between the inferior angle of the rib cage and the iliac crest, approximately in the anterior axillary line. EMG data were amplified 2,000 times, band-pass filtered between 20 Hz and 1 kHz (Neurolog, Digitimer, UK) and
10 sampled at 2kHz using a Power1401 and Spike2 software (CED, UK).

Knee flexion and extension force was measured with a strain gauge (Valydine, USA) attached to the ankle. Force was amplified and sampled with the EMG data at 1 kHz.

Subjects were positioned in supine on a plinth with arms crossed over the
15 chest, the hips flexed to 50 degrees and knees flexed to 90 degrees. In FIG. 1, a subject 10 is positioned on a supporting table or plinth 11. The subject's arms 12 may be crossed over his chest. The legs 13 are supported by a first sling 14 and a second sling 15. The first sling 14 supports the legs behind the knees which are flexed to approximately 90°. The second sling 15 supports the heels. The hips are flexed to around 45°. Although two
20 limbs are described it is possible to use only one limb. Indeed 2 unpaired limbs may be utilised. The limbs are exemplary only and do not restrict the anatomical regions that are suitable for activating a deep muscle.

Two force monitoring devices are provided in the form of transducers 16, 17 each of which is fixed to a support post 18, 19 respectively by a line 20, 21 and to a
25 restraining band 22 on the subject's legs. The force transducers 16, 17 are in signal connection through lead 25 to display means 27 which may be a simple electronic display. Preferably, however, it includes processing means and is preferably a computer. The computer may be programmed to display and store input from the force transducers 16, 17. The computer may also be programmable to manage a testing system including steps such
30 as:

- (1) advising the subject to relax either audible or visually;

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- (2) directing a maximal voluntary contraction in the subject;
 - (3) storing the weight of the subject which may be input through keyboard 28;
 - (4) directing a contraction to a preselected force in the subject in a first
5 direction (eg. extension) and a second direction (eg. flexion);
 - (5) recording details of the assessment session;
 - (6) receiving data on the change of a characteristic of the deep muscle, preferably details of change of width. In one embodiment, these details are entered manually. In a preferred embodiment, electronic data is received from ultrasound device
10 30 through lead 31; and
 - (7) analysing the results to provide an indication of the deep muscle function and/or a propensity to musculoskeletal pain, such as LBP. Preferably, analysing the results comprises identifying change in the characteristic from rest to the first and second activities. If the characteristic does not change or change significantly from rest to
15 one or both activities, or if the change is significantly less in one direction compared to the other, the function of the muscle may be categorised as poor or impaired, thereby indicating a propensity to musculoskeletal pain such as LBP. If the characteristic is thickness of the TrA, an increase of width of 10%, and preferably 20%, may be an indication of adequate to good performance.
- 20 The ultrasound (US) device 30 is in signal connection with transducer 23 through lead 32. The US device 30 has a screen display to facilitate visualisation of the deep muscle of interest. An operator may electronically mark the limits of the width of the muscle, at rest and during the activities. This electronic information may be processed by the computer 27 to provide the necessary indication of change. The computer may be
25 programmed to subtract resting width from the width during the first and second activities. The change may be experienced as a percentage of the resting width and compared with a reference range. If either is below a pre-identified level, such as 10%, the function of the deep muscle may be considered impaired. The pre-identified level may be determined by assessing a group of subjects who have no history of the relevant musculoskeletal pain,
30 such as LBP. The changes may also be compared with each other with significant discrepancies indicating impairment of the deep muscle. Again, the normal range may be

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established by testing a normal group.

The computer may be programmed to analyse the data according to one or more of the following:

$$f_1 = \frac{Wa_1 - Wr}{Wr}$$

$$f_2 = \frac{Wa_2 - Wr}{Wr}$$

$$f_3 = f_1 - f_2$$

where

f_1 = a first indicator of function;

Wa_1 = width of the muscle during the first activity;

10 Wr = width of the muscle at rest;

f_2 = a second indicator of function;

Wa_2 = width of the muscle during the second activity;

f_3 = a third indicator of function.

15 If f_1 and/or $f_2 < fn_1$, where fn_1 is a lower limit for a normal subject, the muscle function may be impaired.

If $f_3 > fn_2$, where fn_2 is an upper limit for a normal subject, the muscle function may be impaired.

An ultrasound transducer 23 is shown positioned in contact with the subject's abdomen.

20 In operation, flexion and extension of the legs is prevented by the fixed lines 20, 21. Force generated is measured by the transducers 16, 17. The measured force may be recorded automatically if provided in digital form. Digital information may be passed to a processing device such as a computer and subject to analysis by one or more suitable algorithms. Changes in the dimensions of the TrA as revealed by ultrasonography
25 may also be electronically recorded and passed onto the processing device. Analysis of the information may be automatic with an indication or result provided by appropriate display or print out. The processing device may be programmed to control the assessment once a patient is in position. It may provide auditory or visual directions to the subject and record changes at appropriate times.

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An auditory feedback device 24 is also provided in order to indicate to the subject when requested assessment conditions are, or are not, achieved, although the feedback could be provided visually.

The legs were suspended by slings wrapped around the knees and ankles
5 and attached to a metal bar placed over the subject. Legs were suspended for two reasons. First, leg support reduces the need to actively hold the legs and allows the trunk muscles to relax prior to the commencement of the task, and second, this position removes friction between the support surface and feet to allow accurate control of force. Knee flexion and extension force was measured with a force transducer attached to a belt strapped around
10 the ankles and a frame that was fixed firmly to the bed.

In the test position, subjects were instructed to remain relaxed prior to testing and then perform isometric knee flexion or extension efforts to target forces based on 7.5% and 15% of their body weight. These force levels were selected from pilot studies which indicated that subjects with no history of LBP activated TrA with forces at these
15 levels. Tasks were performed at small loads as ultrasound has been found to have a linear relationship with force only at contraction levels less than 30%. Previous studies have indicated that the people with LBP may have an increased threshold for activation of the TrA.⁷ The order of directions of movement and contraction levels was randomised and subjects were provided with auditory feedback of force. Two repetitions of each task were
20 performed and static ultrasound images were made at rest and once the target isometric knee flexion or extension force had been reached. All measures were made at the end of expiration, measured with an inductance plethysmograph (Respirace, NIMMS, USA) placed around the chest. Subjects performed two maximal voluntary contractions (MVC) for each muscle for normalisation of the EMG data. For the MVC recordings subjects
25 were positioned supine with the hips and knees flexed to 45 degrees and contracted maximally against manual resistance. The tasks were; a forced expiratory manoeuvre for TrA, and rotation of the trunk to the left for OE and to the right for OI.

FIG. 2 shows a first relaxed ultrasound image 125 and associated schematic representation 126 of the image 125. The OE, OI and TrA are apparent at rest. An
30 ultrasound image of a contraction associated with attempted movement of the legs is shown at 127 and schematically at 128.

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Ultrasound data were measured with custom designed software using LabView (National Instruments, USA). A grid was placed over the image and measures of muscle thickness of TrA, OI and OE were made at three sites; the middle of the image, and sites 1 cm (calibrated to the image scale) either side of the midline (FIG. 2). Cursors were placed on the superficial and deep boundaries of the muscles (the cursor was placed at the edge of the hypoechoic region that represents the location of the fascial separation between the muscles). The average of the three measures was recorded for analysis and the change in thickness was expressed as a proportion of the thickness at rest.

The root mean square (RMS) EMG amplitude was calculated for 1 s at baseline and during contraction (FIG. 3). Measures were made at the time indicated by the trigger aligned to the time the ultrasound images were made. The baseline EMG amplitude was subtracted from that during leg movement efforts and this value was normalised to the RMS amplitude measured for 1 s during the MVC tasks (minus the resting value) for each muscle.

The mean of 2 directions and the minimum values across the two directions were compared. As the results of the two analyses were similar only the mean values are disclosed. It may be useful to also use a ratio of the flexion and extension data in certain circumstances. However this may not be possible because values approach infinity if there is no change in thickness for one direction of movement. Statistical analysis of both ultrasound and EMG data were performed using a two-way analysis of variance with between factors being groups (LBP vs normal) and muscles (TrA, OI, and OE). The alpha level was set at 0.05.

When subjects flexed and extended the knees in supine to a force equal to 7.5% of their body weight there were differences in the change in thickness of the abdominal muscles between groups ($F=6.11$; $P=0.01$), muscles ($F=5.94$; $P<.01$), and an interaction effect between group and muscle ($F=3.23$; $P=0.04$). Post-hoc analysis indicated that the mean increase in thickness of TrA was less for the LBP group ($P<.01$) (FIG. 4). There was no difference between groups for OI ($P=.31$) or OE ($P=.85$).

FIG. 5 shows the data separately for knee flexion and extension tasks for all subjects with efforts targeted to ~7.5% of body weight. In general the increase in thickness was different between movement directions. However, there was individual variation in

the direction with the greatest increase. The increase was greater for flexion for 5 (50%) control subjects and 4 (40%) LBP subjects. Across both directions, 14 (70%) of the control subjects increased TrA thickness by at least 10%, whereas this amplitude of increase in thickness was only achieved for 3 (15%) of the LBP subjects.

5 Similar changes in the thickness of the muscles were found with knee flexion/extension efforts targeted to ~15% of body weight (FIG. 6). There was a significant effect observed for group ($F=6.48$; $P=0.01$), muscle ($F=7.69$; $P<0.01$), and the interaction between group and muscle ($F=4.01$; $P=0.02$). Again the only difference between groups was a larger mean increase in thickness of TrA when control subjects
10 performed isometric flexion and extension efforts than the LBP subjects ($P<0.01$) (FIG. 6). There was no difference between groups for OI ($P=.37$) or OE ($P=.82$). Similar to the tasks performed at 7.5% effort there was variability in the increase in TrA activity between directions (FIG. 5). The increase was greater for flexion for 5 (50%) control subjects and 6 (60%) LBP subjects. In the control group, 15 (75%) values increased TrA thickness by at
15 least 10%, whereas in the LBP group 8 (40%) values reached this level.

Analysis of the EMG data was largely consistent with the ultrasound measurements. When subjects flexed and extended the knee to ~ 7.5% of body weight although the main effects for group ($F=2.37$; $P=0.12$) and muscle ($F=1.12$; $P=0.33$) were not significant, there was a significant interaction effect between group and muscle
20 ($F=3.57$; $P=0.03$). Similar to the change in thickness measured with ultrasound imaging, the mean increase in TrA EMG was greater for the control group than the subjects with LBP ($P=.04$).

When subjects targeted 15% of body weight there was a significant effect for group, with lesser increases in EMG amplitude for the LBP subjects compared to the
25 controls, ($F=6.25$; $P=0.01$), but there was no significant effect for muscles ($F=1.04$; $P=0.35$) or for the interaction between group and muscle ($F=2.39$; $P=0.10$) (FIG. 6).

The results of the present study support previous EMG data that indicate that the automatic recruitment of the deep abdominal muscle, TrA, is modified in people with recurrent LBP when they are in remission from symptoms. Furthermore, the data
30 provide evidence that this altered strategy for trunk muscle recruitment can be measured with ultrasonographic measurement changes in thickness of this muscle during isometric

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leg tasks performed at low effort. This test provides a non-invasive method to investigate the automatic recruitment of the trunk muscles in people with LBP in a clinical setting.

The present inventor has identified activity of the abdominal muscles (measured with ultrasound and EMG) in association with limb tasks as an important prediction of function. Although previous studies have investigated movements of the upper²⁷ or lower limbs,³³ in the present study, tasks were performed isometrically. In general it is considered that this activity is directed at control of the stability or orientation of the trunk against the internal and external forces resulting from limb muscle contraction and movement.^{29 31 34} The subjects were not instructed to contract the abdominal muscles but to concentrate on the leg movement task. Thus, the abdominal muscle activity may represent the automatic strategy for recruitment of the trunk muscles and is not dependent on voluntary effort. While providing a possible explanation for the function of the present invention and associated physiology, the applicant does not wish to be bound to any one theory and makes all such comments by way of observation only.

One feature of TrA recruitment was not consistent with previous reports. Previous studies of arm movement had argued that the amplitude (and timing) of recruitment of this muscle is not dependent on the direction of force.²⁷ In the present study, most subjects had greater recruitment with one direction of movement, but the direction with greatest recruitment varied between individuals. This is likely to reflect the inequality between the knee flexion and extension tasks in terms of muscle activation and stability provided by the support surface, due to variation in individual strategy. One feature of the present invention is that control subjects with no history of LBP activated TrA with both directions of movement, although its amplitude varied.

Two measures of muscle activity were used, intramuscular EMG and ultrasound measurement of change in muscle thickness. The reliability of ultrasound measurement of muscle thickness of the abdominal muscles has been established.^{24 40}

Ultrasound presents several advantages over intramuscular EMG recordings. First, it is non-invasive and may be used in a clinical setting. Second, it provides the opportunity to investigate a larger portion of the muscle than can be recorded with a single intramuscular EMG electrode.

The inventor found that people with a history of LBP use a different

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strategy of trunk muscle activity during isometric leg tasks compared to people without LBP. This could be measured as a difference in the change in thickness of TrA measured with ultrasound imaging. Several issues require consideration. First, the present data are consistent with previous studies that have shown changes in TrA activity in association
5 with LBP. Previous studies have identified delayed activity of TrA with movements of the arm and leg.^{5 6} These changes have been shown to represent a change in motor planning rather than changes in motoneuron excitability⁴¹ and have been replicated when pain is induced experimentally by injection of hypertonic saline.⁴ Although the earlier studies provide evidence of a change in timing in people with LBP, the present data provide
10 evidence of a change in ongoing EMG activity.

The data indicate that the amplitude of activity of TrA was less in people with LBP, for at least one direction of leg task, than for people without LBP. Although the mean of the knee flexion and extension data are reported here, the data was also analysed in terms of the minimum amplitude across directions. The results were similar using this
15 method. This suggests that the threshold for activation of TrA may be greater for the LBP subjects.

EXAMPLE 2

The results of this study demonstrate that the activity of TrA, as measured with ultrasound imaging was similar in highly trained triathletes and sedentary subjects
20 who do not have a history of low back pain. This indicates that despite differences in activity level, activity of TrA, during the performance of low load flexion and extension lower limb tasks by individuals who do not have a history of low back pain (LBP), may not be altered by habitual physical activity levels. However, during the performance of the same tasks activity of the superficial abdominal muscles differed between the groups.
25 Sedentary subjects activated OI, OE and RA to a greater percentage of MVC than the triathlete subjects when subjects performed isometric knee flexion to force levels normalised to their body weight.

Eighteen subjects participated in a study including nine (five male, four female) triathletes and nine age- and sex-matched sedentary individuals. The mean age
30 and weight of the sedentary group was 27.8 years and 79.4 kg. The triathletes mean age and weight was 27.3 years and 65 kg. Recruitment of subjects adhered to strict clinical

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criteria. For inclusion in the triathlete group, the subjects were required to train (running, swimming and cycling) at least 10 hours per week and had participated in at least one competitive triathlon event in the last 12 months. The sedentary group inclusion criteria stated that no physical activity above that required for normal activities of daily living was performed in the last 12 months. Habitual physical activity was measured using a questionnaire developed and validated by Baecke et al, 1982. Subjects were excluded if they had a history of respiratory dysfunction, abdominal surgery in the last two years or a significant history of LBP. A significant history of LBP was defined as LBP in the last two years that resulted in time off work or sport or that which required medical or therapeutic intervention. One sedentary and two triathlete subjects were excluded from the study due to either an inability to adequately perform the tasks or were unable to control their breathing pattern.

EMG has been widely used to evaluate the activity of the superficial abdominal muscles. Silver-silver chloride electrodes were used to record EMG activity of RA, OI and OE muscles. Electrodes placement followed the guidelines developed by Ng et al (1998). Electrodes were placed on the right abdominal wall. EMG signals were amplified (2000x), bandpass filtered (20-1000Hz) and sampled at 2000Hz using Spike2 software and a CED1401 data acquisition system (CED, UK).

Ultrasound (US) images were taken to determine changes in activity of the TrA. Single images were captured using computerised sonography (Acuson 128XP4, CA, USA). An 80mm 5MHz curved array transducer was placed in a dense foam cube midway between the iliac crest and anterior costal margin at a location such that there was two centimetres between the medial edge of the ultrasound screen and the medial edge of the TrA when at rest. To quantify TrA activation, thickness measurements were taken at three points (middle of the image and 1 cm to either side of this point), using custom designed software, within the muscle at rest and during each sustained isometric knee flexion or extension contraction. A trigger marked the EMG trace to allow simultaneous EMG and US recordings. The average change in thickness was used to indicate the extent of TrA muscle activation. It has been established by the inventor that sonographic measurement using this protocol provides a valid and reliable technique for recording the activity of TrA when compared to fine-wire EMG recordings during tasks requiring <20% MVC.

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Knee flexion and extension force was measured with a strain gauge (Valydine, USA) attached to the ankle. Force was amplified, sampled with the EMG data at 1000 Hz and calibrated against known weights.

5 The skin of the abdomen was exposed and prepared in areas needed for electrode placement. The skin was wiped with a gauze swab and alcohol to reduce the skin impedance to below 5 k Ω . EMG electrodes were then applied to the appropriate areas. A respiration band (NIMS, USA) was placed over the thorax at the level of the nipples to record the phase of the respiratory cycle to ensure accurate timing of data collection at the end of a normal expiration.

10 Subjects lay supine similar to as shown in FIG. 1. Both legs were positioned and supported with slings in approximately 60° of hip flexion and 90° of knee flexion. Subjects then performed four isometric knee flexion contractions at force levels equal to 2.5%, 5%, 7.5% and 10% of their body weight, as measured by the strain gauge. These force levels were chosen on the basis of the findings of a study by the inventor and
15 others which indicate that all subjects (untrained adults) recruit their superficial abdominal muscles at a force level equal to 7.5% body weight when performing similar bilateral isometric knee contractions. The task order was randomised for each subject. In order for the subject to produce the appropriate level of contraction, verbal feedback was provided. Once the appropriate level of contraction was reached, the subject was asked to maintain
20 the contraction for approximately five seconds. A frozen US image of the TrA was then taken. A one second trace of EMG recordings was also retrieved and stored simultaneously. Each task was repeated three times in succession with approximately 30 seconds between trials. The subject was then asked to perform the task in a similar manner at the other three force levels and during the knee extension task as well. The EMG and
25 US recordings were made simultaneously. At the completion of the trial, subjects performed a series of maximal voluntary isometric contractions against manual resistance for normalisation of the EMG data.

TrA activation was quantified by averaging the change in thickness of the TrA from baseline over three points within the muscles. The mean of the three values was
30 used in the analysis. Superficial abdominal muscle activity was quantified by calculating the r.m.s of the EMG amplitude for each muscle for the one second time interval recorded

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at rest and during each task. EMG output was normalised and expressed as a proportion of MVC. From the US and EMG data, the activity level was determined for each muscle for every subject.

TrA thickness increase did not differ between the sedentary and elite
5 individuals.

As shown in FIG. 8, RA EMG activity increase was greater for the sedentary compared to the elite individuals.

As shown in FIG. 9, OE EMG activity increase was greater for the sedentary compared to the elite individuals.

10 As shown in FIG. 10, OI EMG activity increase was greater for the sedentary compared to the elite individuals.

The method developed for the present invention provides significant advances above voluntary tests of activation of the abdominal muscles that are commonly reported in the literature.^{10 17 18 25 43} Notably the test does not require learning and
15 motivation is less problematic.

While supported limbs are suitable, this is not essential. One alternative embodiment involves a supine subject raising their leg, preferably bent at the knee. Force transducers or other strain gauges and restrainers are then applied to the thigh, preferably mid thigh region. The subject then attempts to move the leg from left to right and in
20 reverse as the assessment activities. Comparisons of the TrA recruitment may then be made.

There is now strong evidence on the efficacy of specific stabilization exercises in the management of LBP.¹¹⁻¹⁶ The accessibility of a valid measurement of muscle activity will aid clinical judgments when applying this intervention. Clinical
25 outcome and response to treatment are factors that may be assessed by the protocol proposed. The present invention provides a mechanism for the use of ultrasonography, as proposed by the current protocol, to measure changes in muscle recruitment in people with LBP.

The method may be used in an initial assessment of a subject, particularly
30 one displaying symptoms of LBP. A treatment regime may then be instigated and may be based on any appropriate interventions such as exercise and physical therapy. Subsequent

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repeat assessments may be made at intervals such as monthly. Improvements will be apparent as increased recruitment of the TrA as observed on ultrasound imaging. Conversely, no change or a deterioration in muscle activity will provide an indication that the therapy is ineffective.

5 Strategies for the rehabilitation of patients with low back and neck pain involve the restoration of the function of the deep muscles of the spine, followed by the integration of the activity of the deep and superficial muscles in functional tasks. The assessment method described here provides a strategy to obtain an objective measure of the control of the deep muscles. In a clinical setting this forms part of the initial assessment of
10 the patient to determine the extent to which the deep muscles are affected in the individual's presentation. This forms a component of the full assessment undertaken by a therapist. The outcome of the assessment allows the therapist to determine whether reeducation of muscle control should form part of the rehabilitation strategy. Once the extent of muscle dysfunction has been identified the therapist then implements a range of
15 exercises with the aim to restore the normal function of the deep trunk muscles. These techniques are described in detail elsewhere (Richardson CA, Jull GA, Hodges PW, et al. Therapeutic exercise for spinal segmental stabilisation in low back pain: Scientific basis and clinical approached. Edinburgh: Churchill Livingstone, 1999.), but usually include, exercises that involve learning the skilled selective activation of the deep trunk muscles.
20 The assessment methods are then implemented at each intervention to determine the course of recovery of muscle function.

Applications for the assessment method include:

- Assessment at initial consultation for musculoskeletal pain;
- Follow-up assessment during and after rehabilitation;
- 25 - Assessment of risk factors for musculoskeletal pain;
- Assessment for readiness to return to work;
- Assessment to determine requirement for intervention in specific situations such as post partum, post injury and other suitable conditions;
- investigating a symptomatic and/or asymptomatic population.

30 The present invention provides an easy, non-invasive and reliable technique for assessing function of the TrA, in particular, and thereby obtaining an objective

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assessment of the severity of, or tendency to, LBP.

The preferred response in a subject is activity of deep muscles with all directions of movement and activity of deep muscles with lower force levels. Conversely, poor response involves limited activity of deep muscles with one or more directions of
5 force and/or low or no activity of muscles at low force levels.

The advantages of the present method and device are obvious and important. Sufferers of LBP or other musculoskeletal pain may be assessed and effects of ongoing treatment or degeneration quantified with a safe, non-invasive and highly repeatable assessment. The test also has great value for screening potential participants in
10 occupations or activities where stability of the lower back is important especially in an occupational health and safety context. The contribution of the present invention to diagnosis and treatment of one of the most pervasive, chronic and debilitating conditions in the world is of great positive benefit.

Throughout the specification the aim has been to describe the preferred
15 embodiments of the invention without limiting the invention to any one embodiment or specific collection of features. Those of skill in the art will therefore appreciate that, in light of the instant disclosure, various modifications and changes can be made in the particular embodiments exemplified without departing from the scope of the present invention. All such modifications and changes are intended to be included within the
20 scope of the appendant claims.

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The claims defining the invention are as follows:

1. A method for assessing the function of a deep muscle of a subject, the method comprising the steps of:
 - monitoring at least one characteristic of the deep muscle while the subject
 - 5 uses an anatomical structure to perform a first activity and a second activity, each of which cause contraction of the deep muscle in at least some subjects, wherein the first activity and second activity generate respective first and second forces each in a direction different to the other; and
 - analysing results of the monitoring of the at least one characteristic to
 - 10 provide an indication of the function of the deep muscle.
2. The method of claim 1, further comprising the step of monitoring the at least one characteristic at rest and determining changes in the at least one characteristic between rest and the first and second activity.
3. The method of claim 1 or claim 2, wherein the deep muscle is the
- 15 transversus abdominis, the multifidus, the deep cervical flexors or the paraspinal muscles.
4. The method of claim 3, wherein the deep muscle is the transversus abdominis.
5. The method of claim 2, wherein monitoring at least one characteristic of the muscle includes using one or both of ultrasound imaging and electromyographic
- 20 monitoring.
6. The method of claim 5, wherein monitoring at least one characteristic of the muscle includes using ultrasound imaging.
7. The method of claim 3, further comprising the step of recording information on the at least one characteristic and any change that occurs during the monitoring of the at
- 25 least one characteristic.
8. The method of claim 7, wherein the at least one characteristic comprises one or more of the thickness of the deep muscle, the length of the deep muscle and electrical activity of the deep muscle.
9. The method of claim 8, wherein the at least one characteristic comprises
- 30 thickness of the deep muscle.
10. The method of claim 1 or claim 8, wherein the anatomical structure is one

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or more limbs of the subject.

11. The method of claim 10, wherein the limbs are the legs.
12. The method of claim 1 or claim 2, wherein the first activity and second activity are isometric exercises.
- 5 13. The method of claim 2, wherein the first activity and second activity include movement of the anatomical structure.
14. The method of claim 2, wherein the first activity and second activity are each one or more of extension, flexion and rotation or attempts to extend, flex or rotate.
15. The method of claim 2, wherein the first force and second force are
10 separated in a range of 15° to 345°.
16. The method of claim 15, wherein the first force and second force are separated in a range of 25° to 335°.
17. The method of claim 16, wherein the first force and second force are substantially opposed.
- 15 18. The method of claim 1, wherein analysing the results of monitoring at least one characteristic includes identifying any change in the at least one characteristic between the first activity and the second activity
19. The method of claim 2, wherein analysing the results includes comparing
the at least one characteristic when the deep muscle is at rest with the at least one
20 characteristic during the first activity and/or the second activity.
20. The method of either claim 18 or claim 19, wherein comparing a change between the at least one characteristic during the first activity and second activity and at rest may include one or more of subtraction, division, addition, averaging or expressing as a percentage.
- 25 21. The method of claim 18 or 19, wherein analysing the results of monitoring the at least one characteristic includes comparing the results of the subject against a reference database and providing an indication of function and/or tendency to musculoskeletal pain.
22. The method of claim 19, further comprising the step of assessing function
30 of the deep muscle is impaired if changes show one or more of no change in one or both directions between rest and the activities, and decreased change in one or both directions

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between rest and the activities.

23. The method of claim 19, wherein function of the deep muscle is indicated as unimpaired by increases in width by at least 10% and preferably 20% between rest and the first and second activities.

5 24. The method of claim 19, wherein analysing the results of monitoring at least one characteristic includes the step of submitting results to processing means programmed to provide an indication of the function of the deep muscle.

25. The method of claim 2, further comprising the step of minimising the effect of gravity by supporting the anatomical structure.

10 26. The method of claim 25, wherein supporting the anatomical structure comprises the step of supporting at least one limb.

27. The method of claim 26, wherein the step of supporting at least one limb comprises supporting a leg at or around the knee and at or around the ankle.

28. The method of claim 1 or claim 2, further comprising the step of using one
15 or more force transducers or other strain gauges to assess the force of muscle activity.

29. The method of claim 28, further including the step of aligning the force transducers or other strain gauges along a direction of action of the first force and the second force.

30. The method of claim 6, further comprising the step of providing a visual
20 image of the deep muscle during the first and second activity using ultrasound imaging.

31. The method of claim 1 or claim 2, wherein the first activity and second activity include the step of the subject exerting a preselected force within the range of 1% to 30% of maximal voluntary contraction of the anatomical structure.

32. The method of claim 31, wherein the preselected force lies in the range of
25 5% to 20% of maximal voluntary contraction.

33. The method of claim 32, wherein the preselected force is around one or both of 7.5% and 15% of maximal voluntary contraction.

34. The method of claim 1 or claim 2, wherein the first activity and second activity comprise the step of the subject exerting a preselected force which is a percentage
30 of body weight.

35. The method of claim 34, wherein the percentage of body weight is in the

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range of 1% to 30%.

36. The method of claim 35, wherein the percentage of body weight is in the range of 5% to 20%.

37. The method of claim 36, wherein the percentage of body weight is one or
5 both of 7.5% and 15%.

38. A method of assessing the function of a deep muscle of a subject, the method comprising the step of monitoring at least one characteristic of the deep muscle while the subject performs an activity that initiates, at least in some subjects, involuntary activation of the deep muscle.

10 39. The method of claim 38, wherein the deep muscle is the transversus abdominis.

40. The method of claim 38, wherein involuntary activation of the deep muscle is initiated during a first action of an anatomical structure creating a force in a first direction and a second action of the anatomical structure creating a force in a second
15 direction, wherein the first direction and the second direction are separated.

41. The method of claim 40, wherein the first direction and second direction are separated by at least 15°.

42. The method of claim 41, wherein the first direction and second direction are opposed.

20 43. The method of claim 40, wherein the activities are isometric.

44. The method of claim 42 wherein monitoring the at least one characteristic of the deep muscle includes the step of visualising the deep muscle with an ultrasound device and measuring changes in at least one physical parameter of the deep muscle.

45. The method of claim 44, wherein the at least one physical parameter is one
25 or both of the length of the muscle or the width of the muscle.

46. The method of claim 45, wherein the physical parameter is the width of the muscle and the width of the muscle is measured at or around the midpoint of the muscle.

47. The method of claim 46, wherein the width of the muscle is also measured at two positions spaced from and either side of the midpoint.

30 48. The method of claim 46, wherein the changes in the at least one parameter of the muscle are compared between the first activity and/or the second activity and/or the

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muscle at rest.

49. The method of claim 48, wherein the changes in the at least one parameter of the muscle during the first activity and the second activity are compared to a reference range provided by assessment of a plurality of other subjects.

5 50. The method of claim 38, further including the step of minimising or neutralising the effects of gravity during the first activity and the second activity.

51. The method of claim 50, wherein neutralising or minimising the effect of gravity includes the step of suspending a limb or limbs with a support device.

52. The method of claim 38, further comprising the step of identifying a
10 tendency of the subject to suffer from musculoskeletal pain such as lower back and/or pelvic pain by analysing results of monitoring the at least one characteristic and identifying said tendency if changes in the at least one characteristic are absent or decreased in at least one activity.

53. A method of assessing a therapeutic regime or rehabilitation regime for a
15 subject, the method comprising the steps of:

determining a baseline assessment of the function of a deep muscle of the subject according to the method of claim 1 or claim 2;

instituting a therapeutic regime or treatment regime in the subject; and

repeating the assessment of the function of the deep muscle of the subject
20 according to the method of claim 1 or claim 2 on one or more additional occasions and comparing the function of the deep muscle as determined on the one or more additional occasions with the function of the deep muscle at the baseline assessment.

54. The method of claim 53, wherein the regime treatment includes one or more of exercises, pharmaceutical agents, surgery and physical therapy.

25 55. A device for use in assessing the function of a deep muscle, the device comprising patient support means, force detection means and, optionally, limb support means.

56. The device of claim 55, wherein the patient support means is a patient support table.

30 57. The device of claim 55, wherein the force detection means comprises one or more force transducers.

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58. The device of claim 57, wherein the one or more force transducers are each located intermediate attachment means for attaching the force transducer to the limb or limbs and anchoring means for anchoring the force transducer and attachment means.

59. The device of claim 58, wherein the attachment means comprises a cord, a
5 belt and/or a shackle.

60. The device of claim 58, wherein the anchoring means comprises a cord attached to a post.

61. The device of claim 60, wherein the force transducers are locatable in spaced array around the limb or limbs.

10 62. The device of claim 61, wherein the force transducers are separated or separable between 15° and 345°.

63. The device of claim 62, wherein the force transducers are separated or separable between 25° and 335°.

64. The device of claim 63, wherein the force transducers are substantially
15 opposed.

65. The device of claim 65, wherein the limb support means are one or more slings to support the limb or limbs.

66. The device of claim 65, wherein the slings are anchored to a support structure such as a post.

20 67. The device of claim 55, further comprising muscle characteristic monitoring means.

68. The device of claim 67, wherein the muscle characteristic monitoring means is one of ultrasound monitoring means and EMG monitoring means.

69. The device of claim 68, wherein the muscle characteristic monitoring means
25 is an ultrasound device.

70. The device of claim 55, further comprising processing means to analyse the results of monitoring at least one characteristic of the muscle.

71. The device of claim 70, wherein the processing means is a computer in signal connection with the force transducers.

30 72. The device of claim 71, wherein the computer is programmed to control a cycle of testing of the subject including providing a subject with directions as to duration

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and intensity of effort.

73. The device of claim 72, wherein the computer is programmed to perform an analysis of the results of monitoring at least one characteristic of the deep muscle.

74. The device of claim 71, wherein the computer is in signal connection with
5 the ultrasound device.

75. The device of claim 73, wherein the computer is programmed to analyse the data according to one or more of the following:

$$f_1 = \frac{Wa_1 - Wr}{Wr}$$

$$f_2 = \frac{Wa_2 - Wr}{Wr}$$

10 $f_3 = f_1 - f_2$

where

f_1 = a first indicator of function;

Wa_1 = width of the muscle during the first activity;

Wr = width of the muscle at rest;

15 f_2 = a second indicator of function;

Wa_2 = width of the muscle during the second activity;

f_3 = a third indicator of function.

If f_1 and/or $f_2 < fn_1$, where fn_1 is a lower limit for a normal subject, the muscle function may be impaired.

20 If $f_3 > fn_2$, where fn_2 is an upper limit for a normal subject, the muscle function may be impaired.

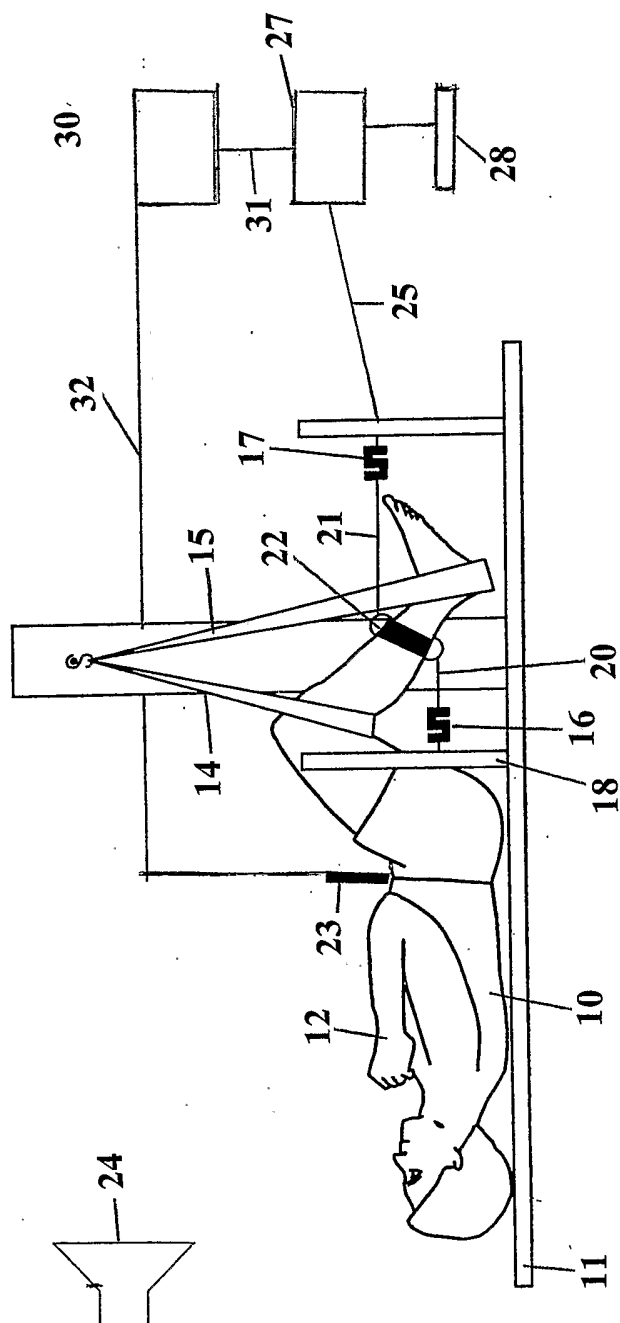
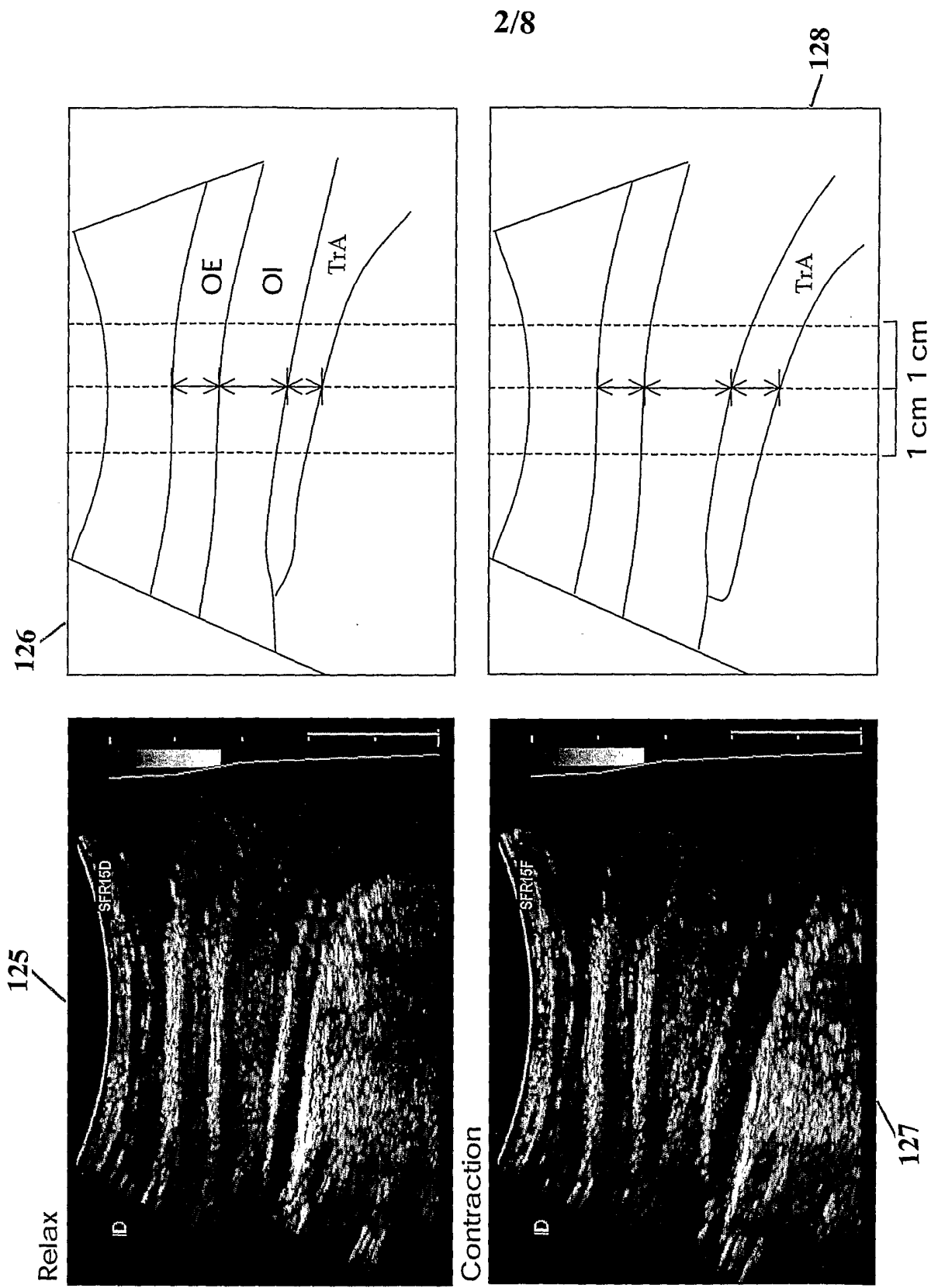


FIG. 1



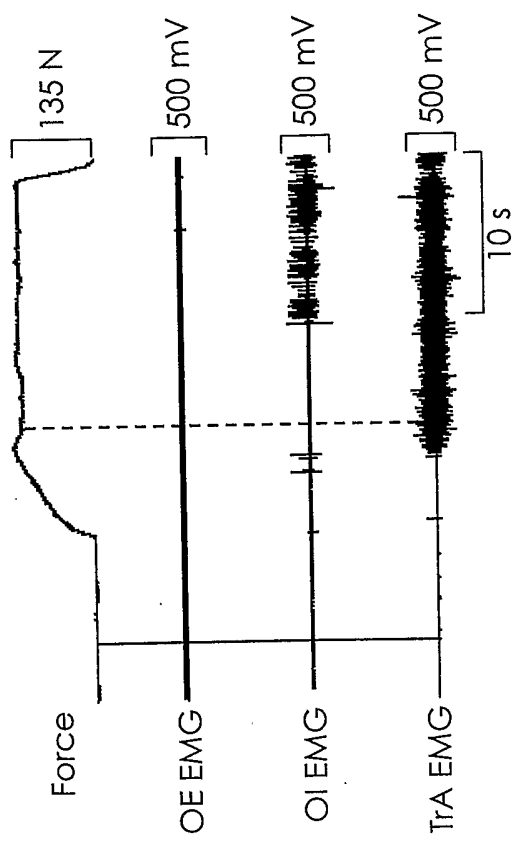


FIG. 3

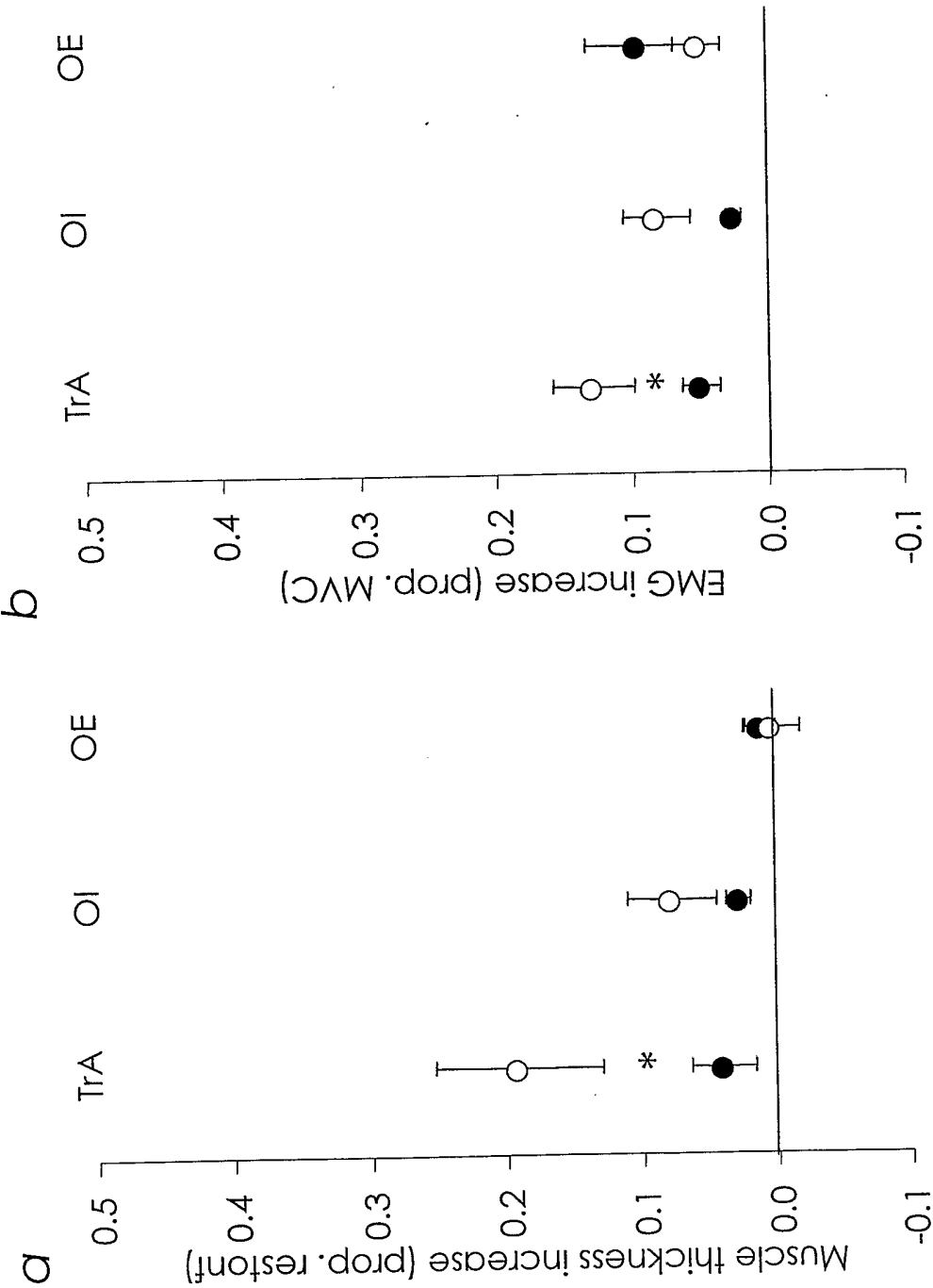


FIG. 4

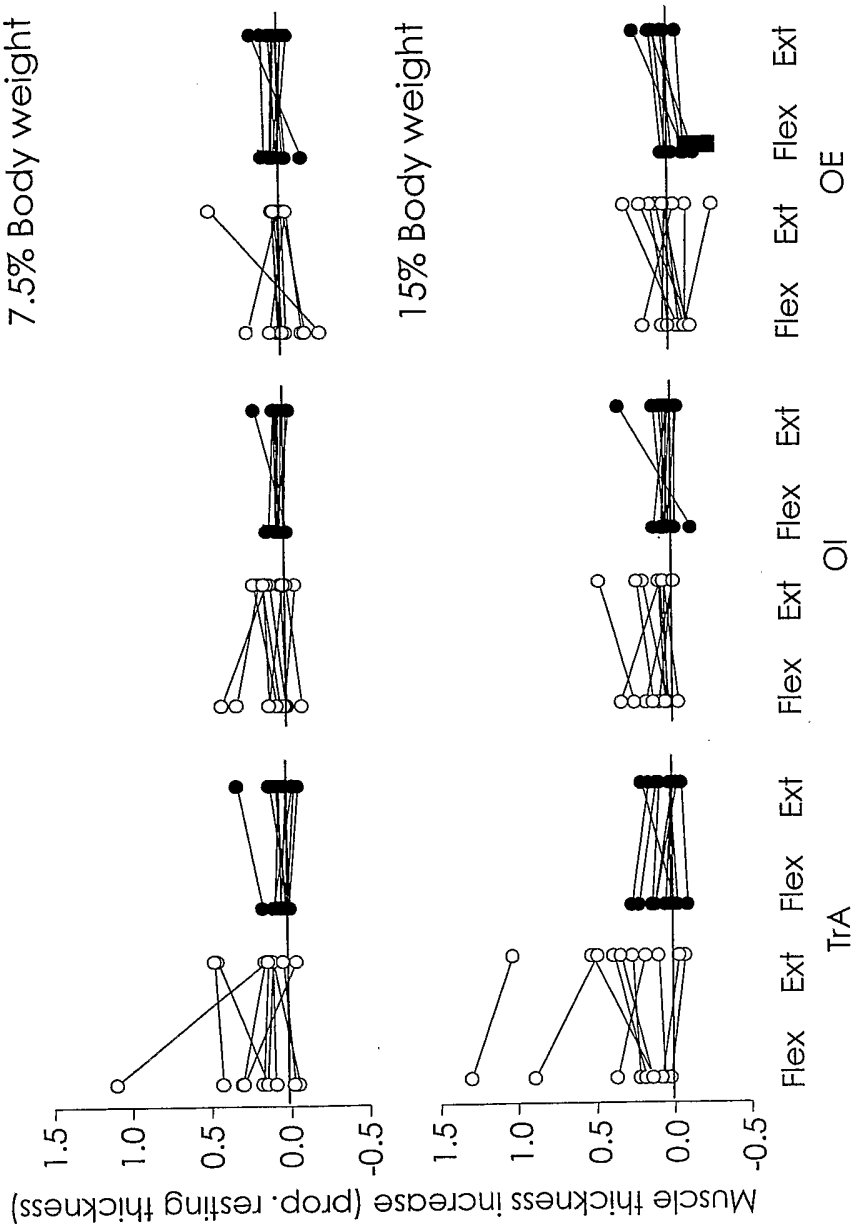


FIG. 5

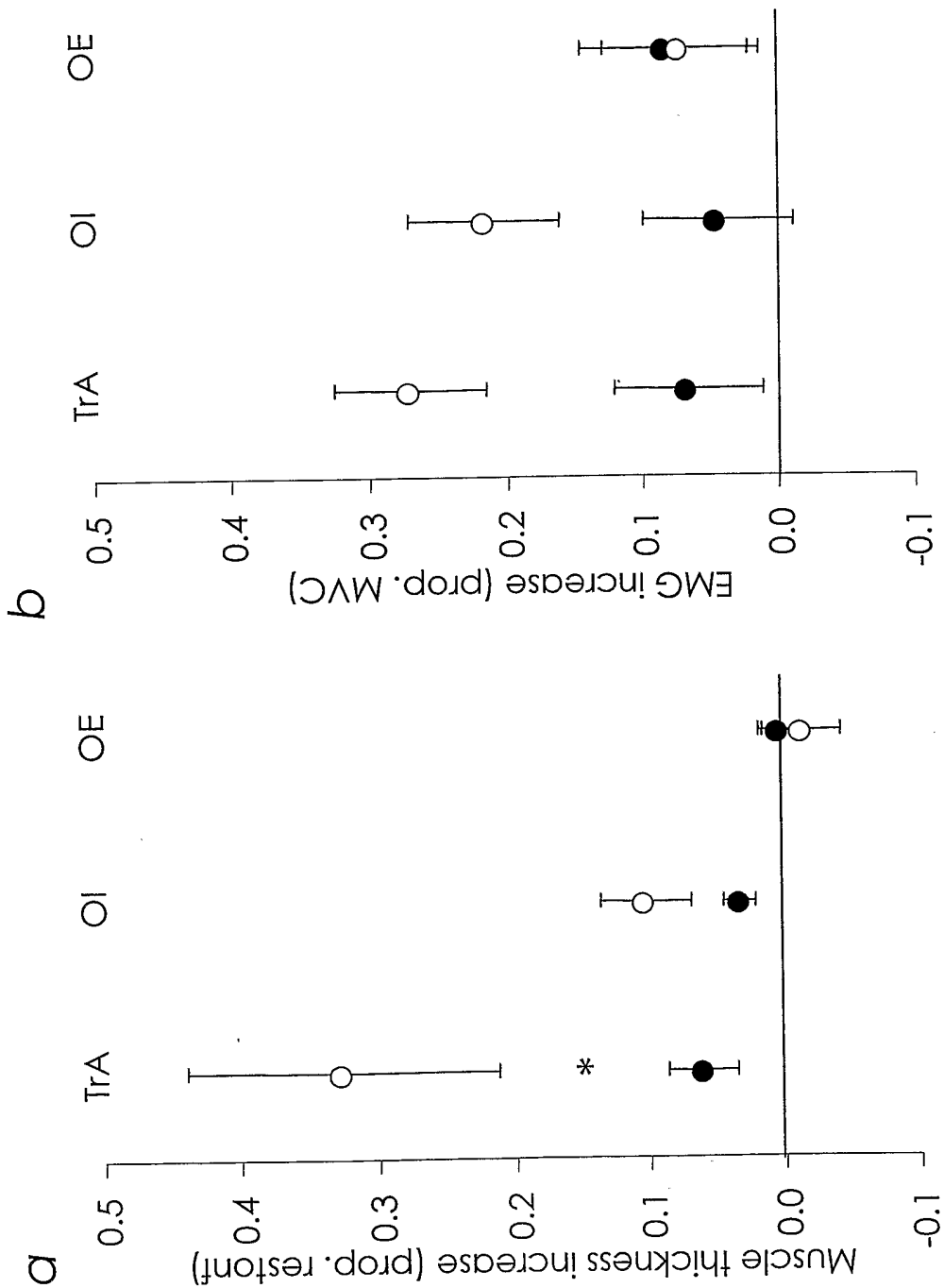
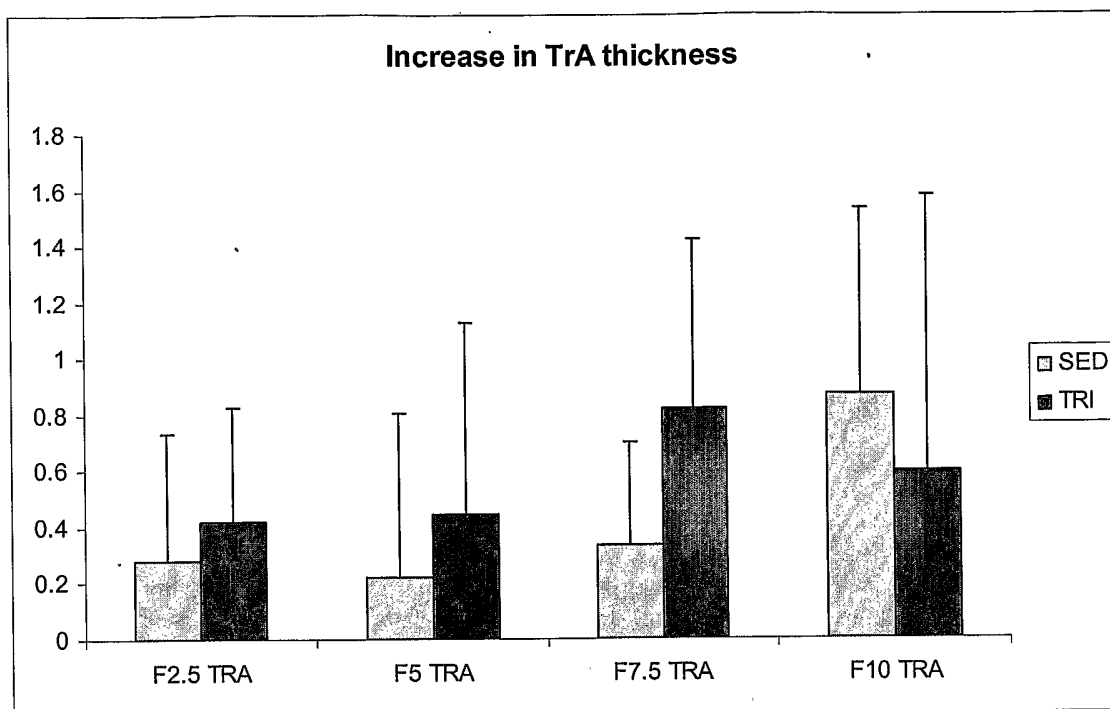
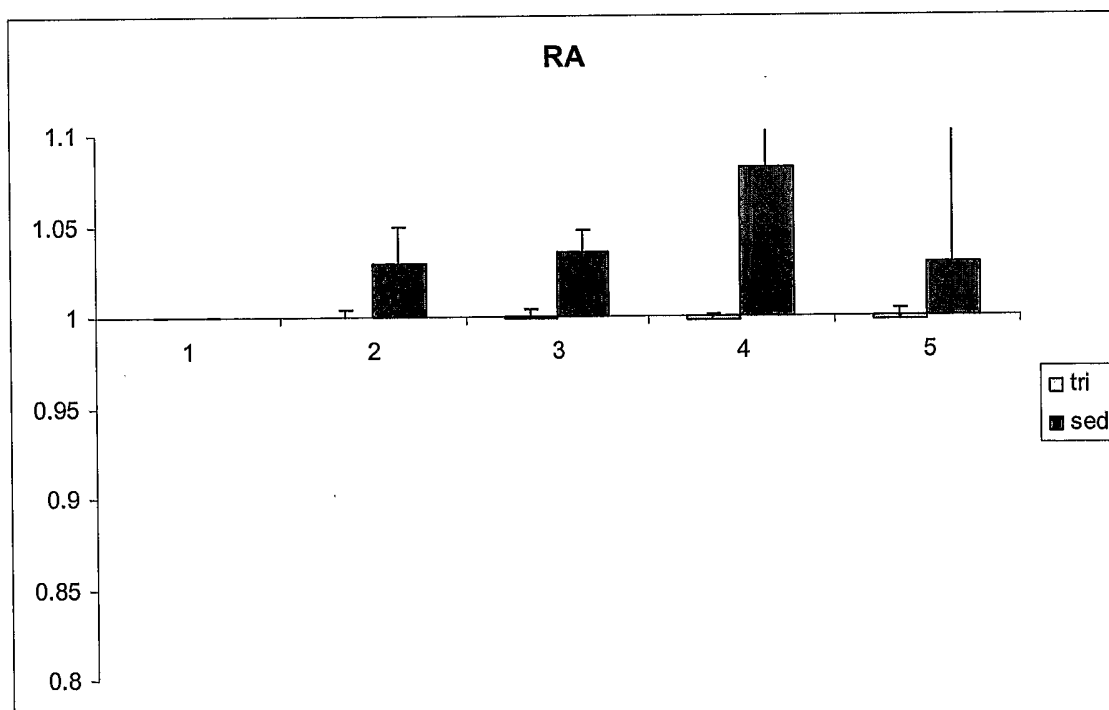
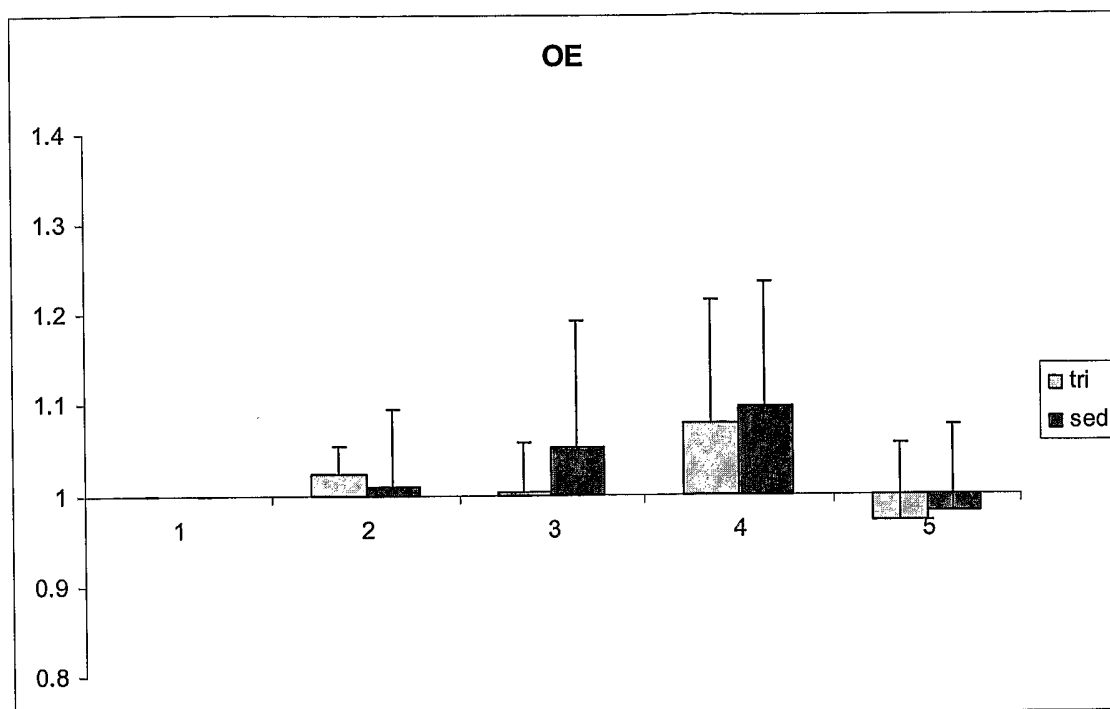
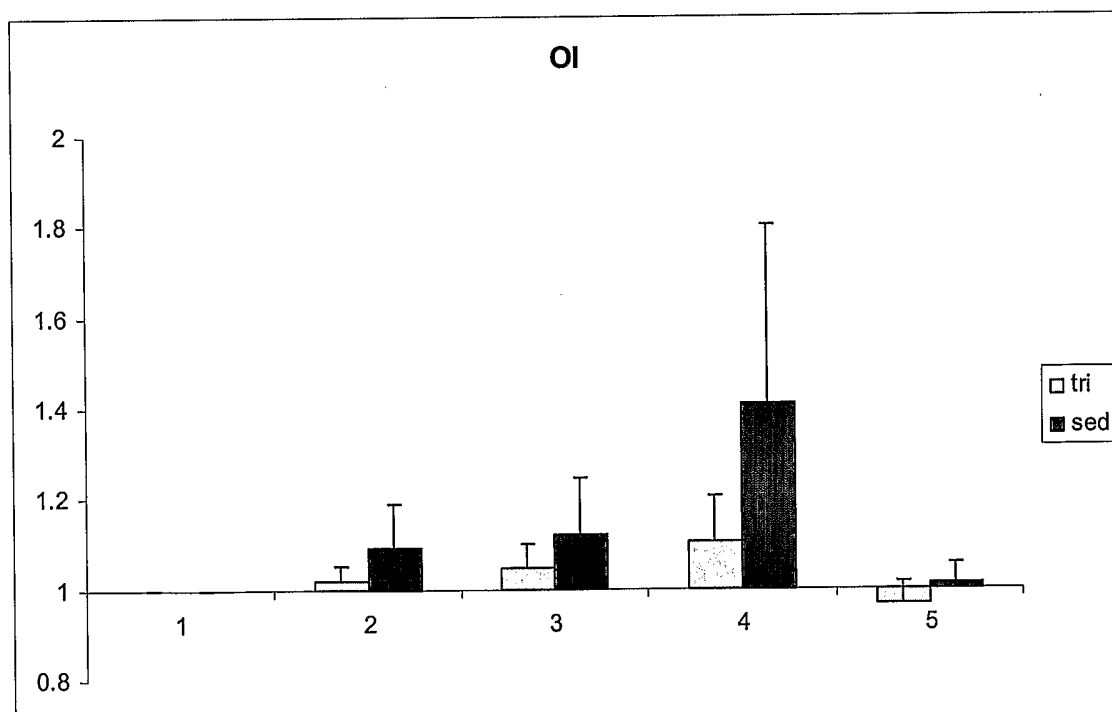


FIG. 6

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**FIG. 7****FIG. 8**

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**FIG. 9****FIG. 10**

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2004/000755

A. CLASSIFICATION OF SUBJECT MATTER Int. Cl. ⁷ : A61B 5/11 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) ELECTRONIC SEARCH AS BELOW Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DWPI (IPC: A61B 5/- ; KEYWORDS: asses+, monitor+, evaluate+, measur+, paraspinal, multifidus, cervical flexors, transversus abdominus, trunk, deep, stabili+, abdominal, muscle, activit+, exercis+, contract+, isometric, action, flex+, force, pressure, load, strain, direction)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6185451 B1 (RICHARDSON et al.) 6 February 2001 See figures 1 and 4, column 5 lines 34 and 35 and claims 9 and 15.	1 to 37 and 53 to 75
X	US 5916172 A (HODGES et al.) 29 June 1999 See figures 1 to 4.	55 to 75
X	US 5086779 A (DeLUCA et al.) 11 February 1992 See figures 1 to 5.	55 to 75
X	US 4845987 A (KENNETH) 11 July 1989 See figures 1 to 14.	55 to 75
☒ Further documents are listed in the continuation of Box C ☒ See patent family annex		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family	
Date of the actual completion of the international search 24 June 2004		Date of mailing of the international search report 08 JUL 2004
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929		Authorized officer PETER T. WEST Telephone No : (02) 6283 2108

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2004/000755

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4732381 A (SKOWRONSKI) 22 March 1988 See figures 1 and 2.	1 to 37 and 53 to 75
X	US 4702108 A (AMUNDSEN et al.) 27 October 1987 See figures 1, 26 to 34 and 40.	55 to 75
X	US 3752144 A (WEIGLE, Jr.) 14 August 1973 See figures 1 and 16 to 19.	55 to 75
A	US 5755675 A (SIHVONEN) 26 May 1998 See figures.	
A	US 4655227 A (GRACOVETSKY) 7 April 1987 See figures.	

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2004/000755

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See Supplemental Sheet.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2004/000755

Supplemental Box

(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: III (Observations where unity of invention is lacking)

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claim 1 is directed to a method of assessing the function of a deep muscle of a subject comprising monitoring a characteristic of the deep muscle while the subject performs a first and second activity which generate respective forces in different directions to each other and analysing the results of the monitoring to provide an indication of the functioning of the deep muscle. It is considered that the subject performing a first and second activity which generate respective forces in different directions to each other comprises a first "special technical feature".
2. Claim 38 is directed to a method of assessing the function of a deep muscle of a subject comprising monitoring a characteristic of the deep muscle while the subject performs an activity that initiates involuntary activation of the deep muscle. It is considered that the subject performing an activity that initiates involuntary activation of the deep muscle comprises a second special technical feature.

Since the above mentioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, a priori.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2004/000755

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report			Patent Family Member				
US	6185451	AU	16398/99	AU	72009/98	CA	2288720
		EP	0979055	NZ	500783	WO	9851215
US	5916172	AU	50968/96	EP	0820253	WO	9629929
US	5086779	NONE					
US	4845987	NONE					
US	4732381	NONE					
US	4702108	NONE					
US	3752144	NONE					
US	5755675	CA	2146120	FI	924455	WO	9407414
US	4655227	CA	1220273				
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.							
END OF ANNEX							