AECC University College
Centre for Biomechanics Research

Information for volunteers:

Low back inter-vertebral motion patterns in healthy adults:
Reference ranges and reliability.

I would like to invite you take part in this research study. Before you decide it is important for you to understand why the research is being done and what it would involve for you. **My contact details are at the end of this information and I would be happy to answer any questions you may have.**

This information leaflet will:

1. Outline the purpose of the research.
2. Explain why you have received this leaflet.
3. Describe what happens next**.**
4. Describe what will happen if you decide to participate.
5. Clarify the risks and benefits to you of taking part.
6. Inform you about confidentiality and data protection.
7. Describe what to do if you have a problem
8. Explain what will happen to the results of this research
9. Tell you who is funding the research
10. State who has reviewed the study
11. Give contact details for the clinical investigator so you can ask any further questions.

1. Purpose.

This study is being conducted to establish a database of the normal mechanics of the low back in people without back pain. This is so there will be a reference for patients being investigated for mechanical pain to help with treatment. A lot of treatment for back pain is based on improving the functional mechanics of the spine, which is reflected in the patterns of inter-vertebral motion. However, until now it has been impossible to measure these in living people without penetrating the skin. Quantitative Fluoroscopy is an X-ray video method doing this which was invented and developed at the AECC University College, where it has been called 'OSMIA' (Objective Spinal Motion Imaging Assessment). This research is to determine the limits of normal inter-vertebral motion so that clinicians who use it in the future will be able to interpret its results and researchers will be able to test the ability of treatments to improve spinal mechanics in living people.

A small number of volunteers will also be asked if they would like to participate in one of three sub-group studies. The first, the 'sEMG sub-study', will investigate the activity of the muscles in the lower back during the OSMIA procedure by measuring the electrical activity produced by your muscles as they contract. This is in order to explore the relationships between the normal mechanics of the low back and the concurrent activity of the low back muscles. The second, the 'MRI sub-study' will investigate the structure of the discs using MRI and relate this to the movement patterns between the vertebrae. The last referred to as the 'Back Motion' sub-study' will establish, for the first time, the dynamic errors associated with measuring spinal motion using markers placed on the skin by comparing these measures to the much more accurate Fluoroscopy measures.

2. Why Have I Received this Leaflet?

You have received this leaflet because you are aged between 21 and 70 years and you replied to and email or advertisement in the College asking for volunteers who fit the inclusion criteria and who would like to take part in this research study. This leaflet will explain the research in further detail.

3. What Happens Next?

After at least a week, I will contact you to ask if you are still interested in taking part. I am happy to answer any questions you may have but it is entirely your decision whether or not you decide to join the study. You are free to refuse to participate or withdraw at any time prior to the taking of the x-ray video without giving a reason (see Confidentiality and Data Protection p6).

4. What Will Happen if I Decide to Participate?

If you take part in this research your name, gender, age, height and weight, address and telephone number and email will be stored on a password protected database. You will be invited to attend the x-ray department at a time convenient to you. I will meet and go through this Information Leaflet with you and explain the examination. If you are happy to proceed you will be asked to sign two consent forms, one of which will be for you to keep.

You will then be allocated to have either a forward-backward bending examination or a side-bending one. You may also be asked to agree to have an additional one in 6 weeks' time and if you are also willing to participate in either sEMG , the MRI, **or the Back Motion** study. You will then be shown to a changing room and asked to change into a gown. We will then show you how the equipment works. OSMIA uses specially designed motion tables and low dose video x-rays. You can view this in advance on the College website if you wish.

https://tinyurl.com/trnw7qu

The tables rotate so that the upper half of the body moves slowly from side to side.

One table is for lying examinations and the other is for standing.

First you will be asked to lie on one motion table. The upper half of the table will swing slowly from forward and back and video x-rays will be taken showing the movement of your vertebrae as you bend. Then you will be asked to move to an upright motion table and stand against it. Again the table will slowly move while you bend, following a moving arm rest, while the x-rays

are taken simultaneously. Before we take the x-rays we will find the range of bending that you are comfortable with.

sEMG sub-study only: If you have agreed to participate in this study it will add approximately 15 minutes to your visit. At the point between the lying and standing examinations, the skin over your lower back region will be prepared for sEMG electrodes (which are self-adhesive pads). This should not be painful, but it does involve abrading the skin lightly with a cloth, cleaning with an alcohol swab and if necessary shaving the area. We will also measure the thickness of a fold of your skin at 3 different levels, both on the left and right sides of your lower back. Fifteen electrodes and three small wireless transmitters will then be placed on the skin of your mid to lower back. This will enable the measurement of your back muscle activity during the standing phase of the examination. In order to get an indication of the maximum activity your low back muscles can produce, at the end of the examination procedure you will then be asked to lie prone on a padded bench with your hands behind your head. You will then be asked to raise your upper body off the couch and hold this position for 5 seconds whilst your legs and pelvis are supported. Finally, when testing is completed you will also be asked a simple question about your experience of the examination procedure.

MRI sub-study only: If you have agreed to participate in this study the additions to the procedure will add approximately 35 minutes to your visit. After the OSMIA procedure, you will be shown into the MR centre which is in the next room. An MR radiographer will show you the equipment and ask you some screening questions. Then you will be asked to lie still in the scanner for approximately 30 minutes. (This is an open scanner so you will not feel claustrophobic.) Then you will be asked to stand still in the scanner for 5 minutes, after which you will be free to go.

If you agree to take part in the MRI study that is repeated 6 weeks later, you will be asked to attend twice. The studies will be done in the morning and you may be asked to wear a special leotard for a few hours before your scan. After the OSMIA and MRI procedures, you will return to your normal attire and be free to go.

<u>Back Motion sub-study only</u>: If you have agreed to participate in this study, the additions to the procedure will add approximately 30 minutes to your visit. After the lying down part of the OSMIA procedure, the skin over your lower back region will be prepared for the attachment of two strips of hypoallergenic tape to your back, one at the base of the rib cage and the other around the belt line. This should not be painful, but it does involve abrading the skin lightly with a cloth, cleaning with an alcohol swab. We will then attach a motion sensor and a reflective marker to each strip of tape. You will then complete the standing up part of the OSMIA study, during which your back motion will also be measured from the sensors that we have attached to your back.

After all the imaging is over, we will ask you to perform some forward and backward bending without fluoroscopy - to calibrate the motion sensor and reflective marker systems. After this we will gently remove the tape from your back and you will be free to go.

During the OSMIA examinations, your lower abdomen will be covered with a lead apron to protect the reproductive organs. You will also be provided with a button that will stop the table should you begin to feel pain or discomfort. The whole OSMIA procedure, including filling in a form, will take no more than 30 minutes. *(If you are also participating in the sEMG sub-study the whole procedure will take no more than 45 minutes, if in an MRI sub-study 65 minutes and if in the Back Motion sub-study 90 minutes.).* We may then make an appointment for you to have the same examination 6 weeks later. Before doing this we will check to make sure you have had no disabling back pain since the first examination. If you have, we will not proceed with the second OSMIA or MRI examination.

5. Risks and Benefits of Participating.

This examination uses x-rays. Therefore it is important you understand the risks and benefits of taking part. Females please note x-rays may harm an unborn child. It is therefore vital that you inform us beforehand if you are pregnant or suspect you might be.

The radiation dose from the examination is roughly the same amount of naturally occurring background radiation you would receive in the UK over a 17-month period. Experts agree that it is very difficult to determine the risk of inducing cancer from such low doses, however it is estimated that there is a 1 in 8.000 – 1 in 13,000 extra chance of getting cancer from this examination. (This is in addition to the quoted 1 in 3 natural lifetime risk of you contracting cancer throughout your lifespan.) You may wish to consider this risk in relation to some more familiar events as in the table on page 5. There is no direct benefit to you from the radiation dose; however, the risk is seen as minimal.

Some familiar risks (Sedgwick and Hall 2003)	Chance they will happen
Getting three balls in the UK national lottery	1 in 11
Needing emergency treatment in the next year after being injured by a can, bottle, or jar	1 in 100
Death by an accident at home	1 in 7100
Getting five balls in the UK national lottery	1 in 11 098
Death by an accident at work	1 in 40 000
Death playing soccer	1 in 50 000
Death by murder	1 in 100 000
Being hit in your home by a crashing aeroplane	1 in 250 000

“Teaching medical students and doctors how to communicate risk." BMJ **327**(7417): 694-695.

There is also a chance that an 'incidental' finding will be seen on your video x-ray. An incidental finding is one that is discovered unintentionally. To date, 60 patients have undergone this examination and there have been no significant incidental findings. I will be reviewing all video x-rays and in the event of an incidental finding you will be referred to your GP if that is what you would like.

Such detection has the benefit of starting treatment early but in a small number of cases may have implications for future employment and insurance. There may be no overall benefit to you from this study but the information I receive might help improve the diagnosis of patients with NSLBP. If you are a student or faculty member you will probably find the experience educational and you will be able to watch the movement of your lumbar vertebrae and see a report on it.

If you agree to participate in the sEMG sub-study, there are no significant additional risks. You may however experience minor discomfort during calliper measurements of skin fold thickness, as a result of skin preparation prior to electrode attachment, or as a result of electrode removal, any of which could possibly result in transient minor red marks on the skin surface. There is also a very slight risk of allergy or irritation caused by the adhesive on the electrodes.

If you participate in the MRI sub-study there are also no significant additional risks.

If you agree to participate in the Back Motion sub-study, there are no significant additional risks. You may however experience minor discomfort as a result of the removal of the skin based marker system, which could possibly result in transient minor red marks on the skin surface. There is also a very slight risk of allergy or irritation caused by the adhesive on the tape which hold these markers on.

6. Confidentiality and Data Protection

Ethical and legal practice will be followed with respect to any information obtained from you in this study. Your details will be kept on a password protected database until all the volunteers

have been recruited. After this, all identifying details will be destroyed. If you enter the study your GP will be informed and you will be asked to provide your GP's details (name and address) on the consent form. Following review of your video x-rays all of your data will be anonymised so you cannot be identified.

Consequently, you will not be able to withdraw from the study once your data have been collected. This does not affect your right to withdraw from the study prior to, or during data collection. Your anonymised data will also be retained indefinitely for use in further studies.

7. What if there is a problem?

If you have a concern about any aspect of the study you should speak to me in the first instance and I will do my best to answer your questions. If you remain unhappy and wish to complain formally you can do this by contacting Professor Haig, the Chief Executive of the AECC University College.

In the event that something does go wrong and you are harmed during the research due to someone's negligence, you may have grounds for legal action for compensation against the AECC but you may have to pay your own legal costs.

8. What will happen to the results of this study?

The results from this study will be anonymised, collated and analysed and published in scientific journals as a reference database. It will also be presented at international conferences such as that of the Society for Back Pain Research. Some data will be referred to on the AECC University College website (www.aecc.ac.uk). You are welcome to keep up to date with the study's progress by periodically checking the website, or by contacting me at any time; my details are at the end of this leaflet.

sEMG sub-group study only: The results from this study may also be published as part of a PhD thesis at Bournemouth University.

AECC University College
Centre for Biomechanics Research

9. Who is funding the research?

This research is being funded by the AECC University College. Additionally, the sEMG sub-study is funded by the European Chiropractors' Union Research Fund (ECURF), the MRI sub-study is being funded by the European Space Agency and the Radiological Research Trust.

10. Who has reviewed the study?

This research has been extensively reviewed by a spinal surgeon, a radiologist, a statistician a medical physics expert, a bioengineer an ergonomist, a chief superintendent radiographer and the South West 3 Research Ethics Committee (REC Reference10/H0106/65). The sEMG and MRI, Back Motion sub-studies have been reviewed by the AECC University College Patient and Public Involvement group and the sEMG sub-study additionally by the AECC University College Research Ethics Subcommittee.

11. Further information and contact details

Professor Alan Breen
Director
Centre for Biomechanics Research
AECC University College
13-15 Parkwood Road
Bournemouth BH5 2DF
Tel: 01202 436275
Email: abreen@aecc.ac.uk