Evaluating the test-retest reliability of a standardized flexion - extension radiograph imaging protocol for the lumbar spine.

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The main objective of this study is to evaluate the test-retest reliability of a standardized flexion - extension radiograph imaging protocol for the lumbar spine. To achieve this, a validated motion analysis technology will be used to quantify…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON57029

Source
ToetsingOnline

Brief title
Flexion-Extension Radiograph Imaging Protocol Reliability Study

Condition

- Joint disorders

Synonym
lumbar spinal stenosis, Spinal instability

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis

Source(s) of monetary or material Support: Medical Metrics;Inc. 2121 Sage Rd;Suite 300;Houston;Texas;USA.

Intervention

Keyword: Clincial, Computer-Assisted, Decision Support Systems, Orthopaedics, Radiographic Image Interpretation, Radiography

Outcome measures

Primary outcome

The main outcome of interest is the agreement between the participants* first

(*test*) and second (*retest*) kinematic results using a validated measurement

technology. The kinematic outcomes include intervertebral translation,

intervertebral rotation and a value derived form the latter:

translation-per-degree-of-rotation.

Secondary outcome

N/A

Study description

Background summary

Lumbar spinal stenosis is a relatively common medical problem, but optimal treatment for the condition is poorly understood. Lumbar spinal stenosis is commonly treated with decompression surgery with or without additional fusion surgery. Orthopaedic surgeons are currently faced with the dilemma of whether or not to add fusion to a decompression procedure. To decide between these two surgical options, surgeons rely mostly on their experience to conclude if a level is unstable preoperatively or if a specific decompression procedure is likely to destabilize the spine. A valid and reliable test for spinal instability would facilitate research to determine whether spinal instability measurements can be used choose the optimal surgical treatment for each level.

Study objective

The main objective of this study is to evaluate the test-retest reliability of

a standardized flexion - extension radiograph imaging protocol for the lumbar spine. To achieve this, a validated motion analysis technology will be used to quantify differences (if any) in kinematic profiles for a patient performing lumbar flexion-extension radiograph according to a standardized imaging protocol and repeating the same procedure one hour later.

Study design

This is an observational, exploratory study conducted in Rijnstate Hospital (Arnhem) and Onze Lieve Vrouwe Gasthuis (Amsterdam) during which participants will undergo one set of flexion-extension radiographs (i.e. two radiographs) and another set of flexion-extension radiographs (i.e two more radiographs) one hour later.

Study burden and risks

Benefits
Participating in this study has no direct benefits for the participants.

Risks
Participants who participate in this study will be exposed to an additional 0.6 mSv of radiation compared to their regular care.

In OLVG and Rijnstate, the effective median exposure dose of a standard lumbar radiograph is 0.2 mSv. During regular care, a patient will typically undergo one anteroposterior and one lateral radiograph, resulting in a total radiation dose of (2 x 0.2 =) 0.4 mSv. The effective dose for a typical flexion-extension radiograph (which is the same as two regular radiographs) of the lumbar spine is also 0.4 mSv. During this study, the participants will undergo one anteroposterior radiograph while their (regular) lateral radiograph will be replaced by a flexion-extension radiograph. After one hour, each participant will undergo another flexion-extension radiograph, resulting in a total study radation dose of (5 x 0.2 =) 1 mSv. This is 0.6 mSv over the radiation exposure during regular care.

Based on a large clinical investigation on the risk to develop cancer associated with exposure to radiation, it was estimated that the excess relative risk for cancer development is 0.97 per Sv [14] . The excess relative risk of the radiation that each subject would receive from participation in this study is therefore calculated as 0.97/Sv x 0.6 mSv x 1 Sv/1000 mSv = 0.000582. To place this relative risk into perspective: there are many sources of exposure to radiation in daily living and the public is exposed to approximately 3 mSv/year from ubiquitous radiation. Also, most patients eligible for inclusion in this study will be over the age of 45. In this latter age group the lifetime risk of radiation induced carcinogenesis is known to decline rapidly.

Considering the above, and applying the risk classification as proposed by the Dutch Federation of University Medical Centers (NFU) the additional radiation risk is negligible (*verwaarloosbaar risico*) because there is only a small risk of minimal damage (*kleine kans op lichte schade*). We believe that the benefits of gaining knowledge about the validity and test-retest reliability of the SPSITM outweighs this negligible risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients...
- must have pain in the back or leg and require lumbar spine radiographs so the orthopaedic surgeon is able to diagnose the probable cause of the pain.
- must be over 18 years of age

- must be able to flex and extend the spine sufficiently to facilitate acceptable flexion and extension radiographs (based on the orthopaedic surgeon*s subjective assessment).

Exclusion criteria

Patients will be excluded from participation if they...
- have any form of spine-related traumatic injury
- have had prior lumbar spinal surgery
- have lateral spondylolisthesis or coronal plane curvature in the lumbar spine of >10°
- duffer from involuntary back muscle spasms
- have significant changes in back or leg pain during the day
- are unable to understand and sign the study Informed Consent Form
- are unable to follow oral instructions.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-11-2024
Enrollment:	45
Type:	Actual

Medical products/devices used

Generic name:	X-ray machine
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-09-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT05633550
CCMO	NL82684.091.22