

Validation Study of 10 subjects with SpineScan3D

SpineScan3D was developed by our research team as a tool to detect back surface topographic changes in spinal deformities. It has the advantages of looking at the spine in 3 dimensions, and capabilities of longitudinal follow-up using data storage in the cloud via the Bluetooth connected Smartphone application. It is envisaged that this tool can be a screening tool for spinal deformities in the paediatric and adult populations, as well as a surrogate for repeated radiographs for patients with routine follow-up assessments.

In order to start the research protocols, we propose all researchers who plan to join our studies to start with this validation study. The aim of this protocol is to verify that the device is being used correctly and all the subsequent data collected will be valid.

Protocol

Subjects

Ten patients with known spinal deformities and due to for radiographic assessment during consultation are eligible for recruitment after informed consent is taken.

Method

Patients should undergo routine radiographic assessments with standing whole spine radiographs with posteroanterior and lateral views taken.

During physical examination, patient should be bent forward and scoliometer reading is taken to measure the angle of truncal rotation (ATR) at the site(s) of the largest hump.

SpineScan3D device is then used to record the back topography detailed as follows:

During the scanning process, the operator, will position the SpineScan3D on the patient's back and roll it on the spine of the object in two postures as illustrated in Fig. 1a "90 degrees forward-bend" and Fig. 1b "Standing" positions.

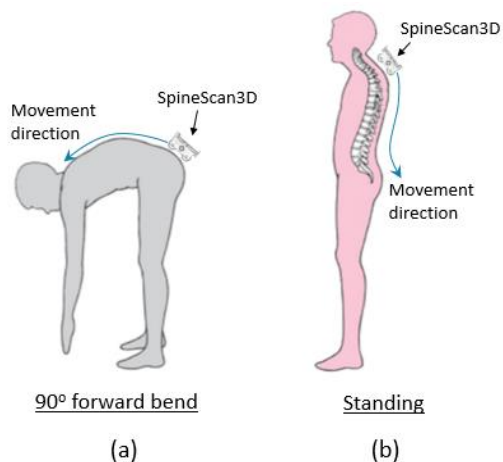


Fig. 1 - Illustrates the screening positions: a) conventional 90 degrees forward-bend position with the SpineScan3D placed at the L5. Operator will press "Start" and then rolls towards T1

following the spinous process of the spine; and b) standing position with the SpineScan3D positioned at the T1. Operator will press “Start” and then rolls downward to L5 following the spinous process. The moving tracks of the SpineScan3D are indicated with the blue arrows on the figure.

This should be performed 3 times on both the forward bending and standing positions.

Data Submission

Please note the unique patient identification number generated by the Smartphone application and cross-reference to the radiographs. The data will be sent to the cloud directly.

All the radiographs should be anonymised and submitted to us, referencing the patient identification number only. Please input the subject’s information in the excel file provided. Kindly submit the excel file together with X-ray images for at least three out of ten subjects via email to us at spinescan3d@ortho.hku.hk.