**RealSpine Validation and Surgical Forces Protocol**

**Objectives**

1. Validation of RealSpine Training system for lumbar decompression
2. Investigation of surgical forces using force sensing gloves

**Study design**

Prospective validation study of RealistSpine Training system

**Participants and setting**

NHNN theatres

* 6 experts
  + Defined as neurosurgical or orthopaedic spinal consultants, or senior spinal surgical fellows
* 12 novices
  + Defined as early stage neurosurgical or orthopaedics trainees who are unable to perform lumbar decompression as primary surgeon

**Surgical task**

Lumbar hemilaminectomy on RealSpine high fidelity model

* Using lumbar spondylolisthesis cartridges
  + 4 hemilaminectomy per cartridge
  + Swab used to cover previous sites
* 30 minutes allows for completion
* Task to be completed while wearing force sensing gloves
* Instruments provided including drill, Kerrison, exoscope
* Facilitator to act as scrub nurse/assistant

**Data collection**

* Video data collected with OrbEye exoscope
  + Time to completion
  + OSAT to be assessed by consultant neurosurgeons
* Validation questionnaire for experts (see below) using 5-point Likert
* Pre-post questionnaire for novices (see below)
  + Data collected include stage of training, previous experience, ISCP assessment
* Surgical forces to be collected using force sensing gloves

**Outcomes**

**Primary outcome**

* Construct validity - OSAT on RealSpine to differentiate novices and experts

**Secondary outcomes**

Face validation

* Single 5-point Likert

Content validation

* 5-point likert
  + All steps present
  + Visual fidelity
  + Haptic fidelity

Criterion (concurrent) validity

* Predictors (Performance on RealSpine):
  + OSAT
    - Total and subscore
  + Time taken
  + Forces
* Outcomes (Performance in real life):
* ISCP PBA score
* Grade/Stage of training
* Months of neurosurgery or spinal experience
* No cases assisted (or observed, or performed)

Construct validity

* Time Novice vs Experts
* Forces Novice vs Experts

**Statistical analysis**

Statistical analysis was performed using R software (R Core Team, Vienna, Austria). For face validity and content validity, one-sample two-tailed statistical tests will be used to determine significance against a neutral score (score of 3 on the 5-point Likert scale. Construct validity to be tested with logistic regression with OSAT (and other metrics) on the Realist spine as predictors, and criterion validity to be determined by linear or ordinal regression analyses.

Parametric statistical testing (t-test) will be used where possible. Failing this, bootstrapping with 10000 repetitions will be used to obtain two-tailed 95% confidence intervals around the mean, and for single-sample testing against neutral score. For comparisons between groups, permutation test with 10000 repetitions will be used as an alternative to t-tests. Statistical significance was defined as p<0.05.