

IRB Study Number: 20161061

Intraoperative Efficacy of Suction Enabled Retraction Device in Lumbar Spine Surgery

National Clinical Trial Number: **NCT03160170**

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1) Protocol Title

Intraoperative Efficacy of Suction Enabled Retraction Device in Lumbar Spine Surgery

2) Objectives*

This is a prospective randomized controlled trial of a new surgical instrument to assess:

- Effects on operative time and efficiency of exposure in open lumbar spine cases.
- Effect on total blood loss during the exposure part of the operation.
- Rate of clogging of suction device.

3) Background*

During spinal surgery, exposure of bony anatomy requires the use of retraction, suction, and electrocautery at the same time. As three instruments are generally used – a Cobb elevator, electrocautery, and suction – an assistant is generally required or the primary surgeon has to switch between the instruments. The resultant juggling of instruments and/or reliance on an assistant can influence operating time and efficiency.

The new device, Suction-Integrated Surgical Tissue Elevator & Retractor [SISTER], is shaped like a Cobb elevator but also has a hollow core allowing suction tubing to be connected. Thus, a single hand can be used to retract and suction at the same time while the other hand separates soft tissue from the bones with electrocautery. This set up which is proposed to be more efficient will be evaluated in this study.

The device is made of high density plastic material and is disposable. The device meets FDA's Medical Device Exemption 510(k) Requirements (Please see uploaded letter from Ludwig Medical Corporation).

4) Inclusion and Exclusion Criteria*

Inclusion

English-speaking patients undergoing Lumbar One to Sacral One open instrumentation performed by attending physicians in the Departments of Neurological Surgery and Orthopedic surgery will be included.

Exclusion

- Age less than 22 years old
- Patients whose procedure will not involve instrumentation

- Patients with prior Lumbar spine surgery involving more than one level
- BMI less than 20 or greater than 35
- Patients with known bleeding conditions (ex: Factor V Leiden, Von Willebrand's,)
- Patients that routinely take anticoagulation medicine (ex. Aspirin 325mg/day, Plavix)
- Operative cases where a single surgeon performs both sides of exposure.
- Pregnant women
- Prisoners
- Adults unable to consent

5) Procedures Involved*

Patients will be selected prospectively and randomly assigned to either the control group (standard exposure technique) or the suction-integrated Cobb group. Randomization will be performed with a coin toss: “best two out of three” style. For example, if “heads” represents the “control” group, 2 out of 3 tosses resulting in “heads” will assign a given patient to the control group, and if “tails” represents the “suction-integrated Cobb group” 2 out of 3 tosses resulting in “tails” will assign the patient to the suction-integrated Cobb group. Randomization will stop once 20 subjects are enrolled in the suction-integrated Cobb group. If at that time, the control group has less than 20 subjects, all subsequent subjects will be assigned to the control group.

During the consent process, patients will be informed that a new instrument may be used during their surgery. The risks of using the device will be explained to the patient, which will include the surgeon’s discomfort when using the new instrument, or failure of the device, which may lead to a delay during the exposure phase of surgery, which could ultimately result in a longer surgery. Surgeons will be given time to become familiar with the instrument. Operative data will be collected.

In the control group, the surgeons will utilize standard exposure technique and instruments. In the suction-integrated Cobb group, surgeons will be provided with the device. Standard equipment will also be readily available in case the surgeon decides for any reason not to use the device. The device will be provided by Ludwig Medical Corporation, the manufacturers of the device.

The following data will be recorded: age, gender, BMI, spinal levels involved, overall operative time, exposure time measured from skin incision until adequate exposure is achieved by the surgeon, blood loss during the exposure, and number of times the suction had to be unclogged.

No postoperative follow up is required.

A total of 40 patients will be randomized, with twenty assigned to each group.

6) Data Management*

All study staff will be CITI certified and will be trained in handling confidential medical information. Data will be stored on a password-protected computer in a secured location. Data will be coded and each subject will be assigned a unique study number. The linking code will be stored separately and will only be accessible to the study team. Only research members approved by the IRB will have access to the data.

Power analyses has determined that 36 subjects (2 groups of 18) would be sufficient to demonstrate a significant effect. The parameters and assumptions of this analysis are as follows: an average exposure time with typical instruments of 30 (± 15) minutes, a 45% reduction in exposure time previously demonstrated in a previous small study with the new device, a 1:1 enrollment ratio for sub-groups, an alpha value of 0.05 for significance, and power value of 80%. Our proposed study size of 40 subjects will therefore confer statistical power.

7) Provisions to Monitor the Data to Ensure the Safety of Subjects

The PI will be responsible for data and safety monitoring. Any suspected or observed breach in data security will be reported to the PI and IRB.

The data collected and planned analyses are described above. Data will be collected before, during, and after each patient's surgery, and will be reviewed by study staff. The trial will be suspended if a breach of security is observed, or harm is demonstrated to subjects.

8) Withdrawal of Subjects

Subjects will be withdrawn from the study if their planned surgical procedure is cancelled or changed in such a way as to no longer meet inclusion criteria for the study. If a subject withdraws from the study, or is withdrawn from the study, the study staff will stop collecting new information about the subject. However, the study team will use the information they have already collected.

9) Risks to Subjects*

The risks associated with this study are largely those of the surgery itself. Additionally, the surgeon may not be comfortable using the new instrument, or the device may fail, which may lead to a delay during the exposure phase of the surgery. Also, as part of this research, there is a possibility of a breach of confidentiality (your private information) of your medical data. We will take adequate steps to protect your confidentiality. In addition, there may be uncommon or previously unknown risks that might occur.

10) Potential Benefits to Subjects*

Patients may benefit from a potential decrease in operative time, anesthesia time, and reduced blood loss.

11) Vulnerable Populations*

Not applicable.

12) Setting

The research will be conducted at Jackson Memorial Hospital.

13) Resources Available

All research personnel are CITI Certified.

Ludwig Medical Corporation will provide 40 devices free of charge for the study.

14) Recruitment Methods

Surgeons in the Departments of Orthopedics and Neurological Surgery will refer eligible patients to the study. Subjects for the proposed study will be those who have already decided to undergo lumbar spine surgery. Subjects will be selected prospectively based on the proposed operative plan and randomized to one of the two groups (control vs suction-integrated Cobb groups).

15) Local Number of Subjects

Forty patients will be included.

16) Confidentiality

- Data will be stored on a password-protected computer in Dr. Côté's office.
- Data will be coded and each subject will be assigned a unique study number. The linking code will be stored separately and will only be accessible to the study team.
- Only those research staff members approved by the IRB will have access to all research related data.

17) Provisions to Protect the Privacy Interests of Subjects

All data necessary and sufficient for the conduct of the study will be collected and stored as described in the "Confidentiality" section. This information will be both identifiable and non-identifiable data. General information will be collected about the patients from the medical records.

18) Compensation for Research-Related Injury

If injury should occur, treatment will be available. If subjects have insurance, their insurance company may or may not pay for these costs. If subjects do not have insurance, or if their insurance company refuses to pay, subjects will be expected to pay. Funds to compensate for pain, expenses, lost wages and other damages caused by injury are not available.

19) Economic Burden to Subjects

This study involves no financial cost to subjects.

20) Consent Process

Participants in this study will have already consented to surgery prior to being approached regarding participation in the study. Any concerns with the study or information collected will be discussed with the subjects.

Prior to surgery, the patient will be approached by the Investigator or one of the Sub-Investigators who will present a sample device and describe its function as well as the goal of the study. The patient will be given an opportunity to ask any questions about the device and the study. If the patient agrees to participate, he/she will be asked to sign the consent form.

Spanish-speaking participants will not be included in this study, as at this time there are no funds to translate the consent documents.

21) Process to Document Consent in Writing

Documentation of the informed consent process will include the following information:

- Consent will be obtained prior to any study related procedures being performed. The ICF will be fully explained and any questions will be answered to the satisfaction of the subject.
- Subjects' will receive a signed copy of the ICF and HIPAA authorization forms. The ICF process will be performed in a language that the subject comprehended fluently. Specific questions asked by the subject will be documented.
- A copy of all executed ICFs and HIPAA forms will be provided to supporting programs/units/entities (e.g. JHS Medical Records and Clinical Trial Office).

22) Drugs or Devices

A company representative will bring the device to the hospital on the day of surgery for each case enrolled in the study. Institutional and legal protocols will be followed in bringing the device to the hospital. Sterile procedures will be followed in opening and employing the device.