

EPAD monitoring of patients
undergoing robotic assisted
laparoscopic genitourinary
surgery.

NCT# NCT03319407

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General Study Information

Principal Investigator: Robert McClain, MD

Study Title: EPAD monitoring of patients undergoing robotic assisted laparoscopic genitourinary surgery.

Protocol version number and date: Version 1. May 4, 2017

Research Question and Aims

Aims, purpose, or objectives:

The brachial plexus and peripheral nerves are susceptible to injury during robotic genitourinary surgery. SSEPs are commonly used to detect pending injury to peripheral nerves. The purpose of the present study is to use SSEP monitoring to determine the incidence and potential causes of significant changes in SSEP waveforms and correlate these changes with neurologic status of the brachial plexus after robotic surgery.

Background:

The EPAD is a Somatosensory evoked potential (SSEP) device intended for use in monitoring a patient's neurological status by recording somatosensory evoked potentials (SSEP) or assessing the neuromuscular junction (NMJ). The EPAD provides information that enables the clinician to detect changes in nerve response waveform amplitude and latency, which may indicate positioning effect nerve injury. The EPAD also provides information that enables the clinician to monitor the depth of neuromuscular block intraoperatively and during recovery. With this information the clinician can take appropriate interventions that will help prevent or ameliorate peripheral nerve injury or post-operative residual paralysis.

The target population for the EPAD includes patients who may benefit from monitoring neurologic responses using somatosensory evoked response stimulation or neuromuscular junction testing. In particular, EPAD is targeted for patients who may be at risk for limb Positioning Effect (PE). PE refers to peripheral nerve impingement related to patient positioning during surgery or prolonged sedation, which may result in numbness, tingling or paralysis.

Study Design and Methods

Methods:

Patients scheduled for genitourinary surgery are often at risk for developing nerve injuries due to intraoperative positioning. The anesthesiologists assigned to the case will notify study team members if EPAD system will be used intraoperatively. The study team members will approach the prospective participants to obtain permission to record data for the study purposes. A verbal consent will be obtained.

The EPAD system (manufactured by SafeOP Surgical Inc., Hunt Valley MD) consists of the EPAD Control box, tablet computer, stimulation and acquisition cables, and stimulation and acquisition surface electrodes. |



The EPAD is small and light and the control box, that communicates with the tablet computer through Bluetooth or USB can be mounted to the OR bed rail.

The computer employs a proprietary algorithm that detects changes in evoked response amplitude and latency and alerts the user to check the waveform view for artifact or potential limb positioning effect. A built-in cautery detection circuit that suspends waveform averaging in the presence of high frequency interference prevents contamination of waveforms.

The EPAD software application is preloaded onto the EPAD tablet touchscreen computer. The application serves as the user interface for the EPAD Control box to input patient and procedure information, adjust stimulus and acquisition parameters, control stimulus delivery, display acquired data, and deliver messages and alerts to the clinician. The clinician is able to insert time locked comments throughout the case indicating any interventions or events. At the end of the procedure the tablet features a report generator that summarizes all data acquisition parameters and waveforms with corresponding measurement values. In the report there is a section for comments and interpretation of results by the user with the final report being available to be printed or exported electronically.

Electrode cables are provided for both stimulation and acquisition and are color coded for correct connection to the EPAD Control box. The stimulator cable connectors are also uniquely keyed to assure correct connection to the Control box. Labeled tabs on each cable indicate the locations for appropriate electrode connections.

Eight surface electrodes are applied to the patient for full patient monitoring. The EPAD Electrodes are wet gel electrodes designed to minimize the amount of skin preparation required. The electrodes are single-use, disposable, and biocompatible for use on intact skin and can be expected to perform as intended for up to 24 hours.

EPAD Setup

- Surface electrodes will be used for both recording and stimulation.
- Bilateral Median and Ulnar Nerves will be stimulated at the wrist.
- Recording electrodes are placed on the cervical spine at C5 with the reference electrode placed on the forehead.
- A dual electrode patch is placed over the dorsum of the right hand with the recording electrode placed over the muscle belly of the first dorsal interosseous muscle for recording of the Train of Four.
- The stimulation frequency is 4.7 Hz with a 300 microsecond pulse set at 50 mA.
- Baselines are automatically established at the beginning of the case and the amplitude and latency of the waveforms measured. Establishment of the baselines is indicated in green shading of the arms on a pictogram. Adjacent to the pictogram are the measured values shown in blue for the baseline and in green for the penultimate waveform.
- A decrease of 50% in amplitude and/or an increase of 10% of the latency of one of the potentials as compared to baseline will trigger an alert, indicated by the limb turning yellow and an audio alarm.
- Continuous monitoring will be performed throughout the surgery.

Data collection:

- Patient demographics: age, sex, weight, height
- Medical history (hypertension, diabetes mellitus, history of smoking)
- Patient positioning intraoperatively (hand, arm, and head position)
- Intraoperative time of positioning in extreme Trendelenburg and or lithotomy position.



- Intraoperative time of resumption of supine position
- Intraoperative time of onset and duration of significant changes in the SSEP amplitude and latency
- Any changes in surgical protocol as a result of reported SSEP changes (i.e. reposition of arms or head.
- Status of SSEPs at the end of the surgery

Postoperative day 1:.

- Study team members will see patients on postoperative day 1 to complete a questionnaire (see attached form)

Resources:

Equipment and pads are readily available in clinical practice as part of standard of care.

Subject Information

Target accrual: 40

Subject population (children, adults, groups): adults, 18 years or older

Inclusion Criteria:

- Patients scheduled to undergo robotic assisted laparoscopic genitourinary surgery
- Patients who are scheduled to have EPAD monitoring as part of their clinical care intraoperatively.

Exclusion Criteria:

- Patients with previous history of polyneuropathy, carpal tunnel, ulnar neuropathy, or similar neurological deficiencies

Research Activity

Check all that apply and complete the appropriate sections as instructed.

1. **Drug & Device:** Drugs for which an investigational new drug application is not required. Device for which (i) an investigational device exemption application is not required; or the medical device is cleared/approved for marketing and being used in accordance with its cleared/approved labeling. (Specify in the Methods section)
2. **Data** (medical record, images, or specimens): Research involving use of existing and/or prospectively collected data.



HIPAA Identifiers and Protected Health Information (PHI)

Protected health information is medical data that can be linked to the subject directly or through a combination of indirect identifiers.

Recording identifiers (including a code) during the conduct of the study allows you to return to the medical record or data source to delete duplicate subjects, check a missing or questionable entry, add new data points, etc. De-identified data is medical information that has been stripped of all HIPAA identifiers so that it cannot be linked back to the subject. De-identified data is **rarely** used in the conduct of a research study involving a chart review.

Review the list of subject identifiers below and, if applicable, check the box next to each HIPAA identifier being recorded at the time of data collection or abstraction. Identifiers apply to any subject enrolled in the study including Mayo Clinic staff, patients and their relatives and household members.

Internal refers to the subject's identifier that will be recorded at Mayo Clinic by the study staff.

External refers to the subject's identifier that will be shared outside of Mayo Clinic.

Check all that apply:	INTERNAL	EXTERNAL
Name		
Mayo Clinic medical record or patient registration number, lab accession, specimen or radiologic image number	x	
Subject ID, subject code or any other person-specific unique identifying number, characteristic or code that can link the subject to their medical data	x	
Dates: All elements of dates [month, day, and year] directly related to an individual, their birth date, date of death, date of diagnosis, etc. Note: Recording a year only is not a unique identifier.		
Social Security number		
Medical device identifiers and serial numbers		
Biometric identifiers, including finger and voice prints, full face photographic images and any comparable images		
Web Universal Resource Locators (URLs), Internet Protocol (IP) address numbers, email address		
Street address, city, county, precinct, zip code, and their equivalent geocodes		
Phone or fax numbers		
Account, member, certificate or professional license numbers, health beneficiary numbers		
Vehicle identifiers and serial numbers, including license plate numbers		
Check 'None' when none of the identifiers listed above will be recorded, maintained, or shared during the conduct of this study. (exempt category 4)	<input type="checkbox"/> None	<input checked="" type="checkbox"/> None



Power Statement:

N/A

Data Analysis Plan:

Descriptive statistics will be used to present information about study participants' demographics. Correlation analysis will be performed to calculate correlation between reported incidence of residual weakness or numbness and values obtained by EPAD monitoring system.