APPENDIX III. Detailed Study Procedures

Patients who are planning to undergo bilateral carpal tunnel release surgery by one of the hand surgeons listed as an investigator and who meet the additional inclusion/exclusion criteria listed in this protocol were approached by study personnel to see if they would like to participate in this study. Patients were approached in the privacy of an exam room and had ample opportunity to ask any questions they may have regarding participation, the surgical procedure, the anesthesia options, etc. Once all of the questions had been answered, the patient was asked to sign the informed consent document and the HIPAA document. The patient was then asked to complete a QuickDASH questionnaire and a Beck Anxiety Inventory. With the aid of the patient's input, study personnel completed a Baseline Demographic Information sheet for each patient. On this day, patients received the randomization order.

The next study time-point was the day of the first surgery. The patient filled out a Beck Anxiety Inventory while in the pre-operative holding area. When the patient presented for initial follow-up after surgery, they were asked to complete a Post-Operative Questionnaire. These two steps were repeated for the second carpal tunnel release surgery.

The treatment for carpal tunnel syndrome with surgical release of the transverse carpal ligament and other compressive structures is standard for all hand surgeons and has been shown to be done safely via open or endoscopic technique. The anesthetic choices for carpal tunnel release include local anesthetic only or local anesthetic with sedation. These anesthetic choices are both standard and common procedures and have both been shown to be safe.

The most common practice is for the surgeon to use the same technique and anesthetic during surgery on both wrists when a patient chooses to undergo bilateral carpal tunnel release. For this study, the surgeon utilized whichever surgical (open or endoscopic) technique was preferred. However, local-only anesthesia was used for one wrist and local with sedation anesthesia for the other wrist. This may be a deviation from regular practice and was performed only if the patient provides consent to participate in this study. Details about the anesthetic protocols utilized for local-only and sedation procedures are found in Table 1 of this appendix.

Table 1. Protocols for local-only and sedation carpal tunnel releases

Local-Only • 10 – 20 mL 1% lidocaine with 1:100,000 epinephrine and 8.4% bicarbonate (compounded 4:1) administered in pre-operative holding • Incision within 15 – 30 minutes after completion of anesthesia injection • No tourniquet
Local Anesthesia with Sedation • 10 mL of 1:100,000 epinephrine and 8.4% bicarbonate (compounded 4:1) administered following confirmation of patient sedation by the anesthesiology team • Tourniquet applied and inflated to 250 mmHg to produce an immediately bloodless surgical field

It was left up to the discretion of the Department of Anesthesia to follow a standard of care treatment for carpal tunnel release surgery where local anesthesia with sedation is used. Therefore, the anesthesiologist assigned to each surgery decided which drug(s) would be used for sedation. These were recorded during review of the surgical records. Standard precautions before and after carpal tunnel surgery were taken as usual.

Once enrolled in the study, patients were followed for a total duration of 6 weeks after the second carpal tunnel release. During the six-week follow-up appointment, the patient was asked to complete another Quick DASH questionnaire. If a patient decided to withdraw from the study at any time, they were asked to complete the brief withdrawal questionnaire.

After each surgery, the patients operative record was reviewed to collect the amount of time the patient was in the surgery center, preoperative suite, OR suite including tourniquet time, and recovery suite. Anesthetic drugs given were also reviewed.

After each patient's billing cycles for both surgeries have passed, total cost and revenue information from the billing department were obtained to analyze the differences in costs between procedures.

The subjects' personal health information remained confidential and protected by being included in a spreadsheet that was stored exclusively on a HIPAA compliant drive on the OSUMC network. Personal information such as patient name and medical record number were only stored until the end of the study once data analysis was complete.

The surgeons completing the surgeries were asked to complete a questionnaire. This questionnaire collected information from the surgeon at 4 different time points (prior to patient enrollment, after each surgery, after both surgeries and at the end of the study) about clinical preference to anesthesia.