Protocol Title: Effect of Indwelling Foley Placement, Immediate Post-Operative Straight Catheterization, or No Catheterization on Post-operative Urinary Retention After Transforaminal Lumbar Interbody Fusions

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Investigator: Dr. Kern Singh
Contact Information: 1611 W Harrison Suite #300
Chicago, IL 60612
(312) 432-2435

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RUSH

Subject Information Sheet and Consent Form

Introduction

You are being invited to take part in this research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the information in this form carefully, as it may contain words you do not understand.

You may wish to discuss it with your doctor, family, and/or friends. If there is anything that you do not understand or you would like more information, please ask questions and the study doctor or study staff will try their best to answer them. Once the study has been explained and you have had all your questions answered to your satisfaction, you will be asked to sign this form if you wish to participate. Before anything is done for this study, you must sign this form. A copy of this signed form will be given to you.

You do not have to take part in this study. You are free to withdraw from this study at any time you choose without giving a reason. This will not affect any future care you will receive. No promises can be made about the outcome of this as far as your current condition, either positive or negative. People who take part in research are called "subjects" instead of "patients".

Why are you being invited to participate in this study?

You are being asked to take part in this study because you are undergoing a primary, single-level transforaminal lumbar interbody fusion procedure (spine surgery).

What is the purpose of this study?

The purpose of this study is to determine if there is a difference as to when or if a Foley catheter (a flexible tube which is passed through the urethra and into the bladder to drain urine) is placed and which produces the lowest rates of post-operative urinary retention (POUR) or complications after transforaminal lumbar interbody fusions (TLIFs). POUR is one of the most common post-operative complications after elective spine surgeries.

How many study subjects are expected to take part in the study?

If you decide to volunteer for this study, you will be one of 120 subjects expected to participate at Rush University Medical Center.

What will you be asked to do?

After signing the consent, you will undergo a physical examination. At least two x-rays of your lumbar spine (lower back) will be taken. Information will be collected about your medical history, height, weight, age, gender, smoking status, current diagnosis, previous spinal surgery,

any allergies you may have and any medications that affect pain or bone growth that you are taking. You will also be asked about the pain and/or disability you are experiencing. This information is routinely collected for all patients undergoing this surgery and will also be collected as part of the study.

Your surgery and follow-up visits are considered usual for this operation. You will be randomized (assigned by chance, similar to a roll of dice) into 1 of 3 groups:

- indwelling foley catheterization (catheter is placed in the operative room immediately prior to the spine procedure and removed the following morning),
- straight catheterization (in-and-out straight catheterization that will take place at the end of the surgery), or
- no catheterization during your spine surgery.

All 3 groups are considered standard of care.

You can expect to remain in the hospital for 1 to 4 days following the surgery. Before your hospital discharge, the study doctor will talk to you about any medications you may need to take, and you will be provided with recommended post-operative care instructions.

Prior to surgery and at each follow-up visit after surgery you will be asked to fill out questionnaires at 6 weeks, 3 months, 6 months, 1 year and 2 years. These questionnaires are the Pain Visual Analog Scale (VAS), Oswestry Disability Index (ODI), PROMIS (Patient Reported Outcomes Measurement Information System) and the Short Form-12 (SF-12) Health survey. These questionnaires will assess your pain levels, disability, well-being, and perceptions about your health before and after surgery. The usual follow-up care following TLIF surgery includes a clinic visit, x-rays, and several questionnaires.

To evaluate the effect of the implant on your symptoms, you will have evaluations shortly after surgery, and you will be asked to return to the study doctor's office at the following time points:

- 6 weeks
- 3 months (12 weeks)
- 6 months
- 12 months
- 24 months

How long will you be in the study?

You can expect to be in this study for the length of your usual follow-up for TLIF surgery, which is approximately 2-years. You may be removed from this study without your consent. Possible reasons may be that the study doctor decides that continued participation in the study will be harmful to you, you will need a treatment not allowed on the study, your disease becomes worse, you are unable to have the procedure as directed, or the study is canceled.

What are the possible risks of the study?

The potential risks of catheter insertion include, but are not limited to, a urinary tract infection (UTI), pyelonephritis (infection in the kidneys), sepsis, and potential injury with insertion and discomfort.

Your surgery is considered the usual care treatment for degeneration of the lumbar spine. The risks of the surgery (listed below) are the same whether you take part in this study or not. There are no added risks of surgery if you decide to participate in this study. A surgical consent form

administered by your surgeon explains the risks of the transforaminal lumbar interbody fusion surgery.

The risks of surgery and anesthesia (medication used to keep you asleep during surgery) for study subjects are the same as the risks of surgery and anesthesia for non-study patients. The most common risks for this type of surgery include bleeding, dural tear (in the membrane around the brain and spinal cord), neurologic (brain or spinal cord) injury and infection. Anesthesia is safe for most patients; however, there are some risks, for example reaction to anesthetic medications. To minimize the risks of anesthesia, general anesthetics are only given by, or under the immediate supervision of a medical doctor trained to use them.

Are there benefits to taking part in the study?

The primary benefit of catheter insertion is preventing urinary retention post-operatively.

There may be no direct benefit to you for participating in this study**.** This study may possibly improve surgical care for patients in the future undergoing spine surgery.

What other options are there?

The only alternative to participating in this study is not to participate.

What about confidentiality of your information?

Records of participation in this research study will be maintained and kept confidential as required by law. Medical records and material from this treatment are stored and kept confidential according to legal requirements.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Your identity will not be revealed on any report, publication, or at scientific meetings.
In order to conduct the study, the study doctor, Dr. Kern Singh, will use and share personal health information about you. This includes information already in your medical record, as well as information created or collected during the study. Examples of the information that may be shared include your medical history, physical exam and laboratory test results. The study doctor will use this information about you to complete this research.

Confidentiality and disclosure of your personal information is further described in the attachment to this form. The attachment is titled HIPAA Authorization to Share Personal Health Information in Research (2 pages).

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human subjects.

What are the costs of your participation in this study?

All costs that are part of your usual medical care, such as surgery and follow-up visits, will be charged to you or your insurance company. You will be responsible for all costs that are not paid by your insurance company. You should check with your insurance company before you

enroll in this research study. There will be no additional costs associated with which group you are placed into.

Will you be compensated or paid?

Your participation in this research study will not be associated with any compensation or payment.

Your participation in this research study may contribute to the development of commercial products from which the Sponsor company or others may derive economic benefit. You will have no rights to any products, patents or discoveries arising from this research, and you will receive no economic benefit.

What happens if you experience a research related injury?

If you experience any injury or illness as a direct result of your participation in this research study, immediate treatment will be provided. However, the cost of that treatment will be billed to you or your insurance company. Please check with your insurance company regarding coverage.

If you have any medical problems during the study, please contact the study doctor. He will explain your treatment options to you and/or help you find a place to get treatment.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

What happens if you need emergency care?

If you need emergency care while you are participating in this study, it is important that you tell emergency personnel of your participation in this study and notify the study doctor as soon as possible.

Whom do you call if you have questions or problems?

Questions are encouraged. If there are any questions about this research study or if you experience a research related injury, please contact: Dr. Kern Singh at (312) 432 - 2435. Questions about the rights of research subjects may be addressed to the Rush Research & Clinical Trials Administration Office at 1-800-876-0772.

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form.

SIGNATURE BY THE SUBJECT:

Name of Subject	Signature of Subject	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the subject I further attest that all questions asked by the subject were answered to the best of my knowledge.

Signature of Individual Obtaining Consent	Date of Signature

☐ *Check here if the Individual Obtaining Consent observed the signing of this consent document and can attest, to the best of their knowledge, the person signing the consent form is the subject and the person signing the form has done so voluntarily. By checking this box, the Individual Obtaining Consent does not need to sign on the Witness signature line (below).*

SIGNATURE BY WITNESS/TRANSLATOR
(for use if this consent is being used as a written summary of the research along with a short form consent OR when the person obtaining consent is not the witness):

I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the subject and the person signing the form has done so voluntarily.

Signature of Witness/Translator	Date of Signature

☐ Check here if a separate witness signature is not necessary.

SIGNATURE OF THE PRINCIPAL INVESTIGATOR
I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

Signature of the Principal Investigator	Date of Signature

☐ Check here if Principal Investigator obtained consent and a separate signature is not required.