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Title of Study: **Stand-Alone Cage versus Anterior Plating for 1-2 Level Anterior Cervical Discectomy and Fusion. A clinical and radiographic analysis**

Sponsor: **Rush University Medical Center**
Department of Orthopedic Spine Surgery

RUSH

Subject Information Sheet and Consent Form

Introduction

You are invited to volunteer 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 following information 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.

You do not have to take part in this study. If you agree to take part, you will be asked to sign this form. Your signature means that you have read or had this form read to you and you have had all your questions answered by the study doctor or study staff. Before you have anything done for this study, you must sign this form. A copy of this signed subject information sheet and consent form will be given to you. You will be 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 agree to be a part of a research study are called "subjects" instead of "patients".

Why are you invited to participate in this study?

You are being asked to participate in this study because you have degenerative changes in your cervical spine (the neck portion of your spine) and you are scheduled for an anterior cervical discectomy and fusion (ACDF). An ACDF is a fusion surgery between two bones in the neck done from an anterior (front) approach.

What is the purpose of this study?

The purpose of this study is to compare the clinical results between two different techniques for ACDF: 1. Stand-alone ACDF, which means the placement of an interbody device (cage) without anterior fixation or plating; 2. ACDF with and interbody cage and anterior plating for fixation. Both of these procedures are commonly performed at Rush with unclear advantage of one procedure over the other. Both have been associated with good to excellent clinical outcomes. The devices used in this study are approved by the Food and Drug Administration (FDA).

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

This study takes place only at Rush University Medical Center and is sponsored by the Department of Orthopedic Spine Surgery at Rush. If you decide to volunteer for this study, you will be one of approximately 128 subjects that participate. We plan to randomly assign (select by chance like the toss of a coin) 64 subjects in each of the two groups (Group 1: Stand-Alone 1-2 level ACDF, Group 2: 1-2 level ACDF with anterior plating).

What will you be asked to do?

If you are a candidate for an ACDF (anterior cervical discectomy and fusion surgery), you will be presented with the option to volunteer for this study. After signing the consent, you will undergo a physical examination. At least two x-rays of your cervical spine 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 metabolism that you are taking. You will also be asked about the pain and/or disability you are experiencing. These data are already routinely collected for all patients undergoing this surgery and will also be collected as part of the study.

Each subject will randomly be assigned (selected by chance – like a flip of a coin) to Group 1 or 2. Your surgery and follow-up visits are considered usual for this operation. At each follow-up visit and prior to surgery you will be asked to fill out pain questionnaires at 6 weeks, 3 months and 1 year. The usual follow-up care following ACDF surgery includes a clinic visit, x-rays, and pain questionnaires.

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 ACDF surgery, approximately 1-year. You may be removed from this study without your consent. Some possible reasons may include the study doctor deciding 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 indicated, or the study is cancelled.

What are the possible risks of the study?

Your surgery is considered the usual care treatment for degeneration of the cervical 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 study doctor explains the risks of the anterior discectomy and fusion surgery.

The risks of surgery and anesthesia 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 (hematoma), dural tear (in the membrane around the brain and spinal cord), neurologic (brain or spinal cord) injury and infection. Anesthesia (medicine used to keep you asleep during surgery) 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.

Swallowing problems are a potential risk after ACDF surgery, Approximately 20% of patients may have swallowing problems after 6 months, which improves to less than 13% after two years.

Although rare Stand-alone (without plating) ACDFs may have problems with implant subsidence or shifting, and postoperative kyphosis (forward flexion of neck) in radiographic analysis. However, many studies have not found significant associations between this finding and worsened clinical outcomes, compared to plated patients.

As part of your management and this study, x-rays (pictures) will be taken of your spine. These x-rays would normally be acquired by your doctor as usual of care during your pre-surgery evaluation and post-surgery follow-up visits. X-rays are a type of radiation. The amount of radiation that you would be exposed to in this study is very small and less than the amount of radiation that is known to cause a measurable harmful effect. You will be exposed to the same amount of radiation x-rays as you would if you take part in this study or not.

Are there any anticipated pregnancy risks?

Women

If you are pregnant or breastfeeding, you cannot take part in this study. A pregnancy test **is** required and will be given prior to surgery. You are responsible for using an effective birth control method such as birth control pills, barrier method (such as condoms or diaphragms), intrauterine device (IUD), hormone implants or surgical sterility while you are taking part in this study. You may discontinue birth control after the study is complete or after speaking with your study doctor. If you become pregnant, you must notify the study doctor immediately. A pregnancy test will not be performed before each follow up x-ray. The American College of Radiology states that x-rays are safe in pregnancy as the radiation exposure is below the level that increases the risk to the fetus. If you have further questions regarding the safety of an x-ray

study, please ask your doctor or one of the investigators in this study

Are there benefits to taking part in the study?

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?

Instead of participating in this study, you may choose another form of treatment such as:

- Undergo the procedure without participating in the study. You and your physician will then decide based upon his experience and your best interest which treatment modality will benefit you the most.

What about confidentiality of your information?

Records of participation in this research study will be maintained and kept confidential as required by law. A description of this study will be available on http://www.CLINICALTRIALS.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

In order to conduct the study, the study doctor, Kern Phillips, MD, will use 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 used 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 entitled HIPAA Authorization to Share Personal Health Information in Research (2 pages).

Your identity will not be revealed on any report, publication, or at scientific meetings.

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 pre-operative visit, surgery, and follow-up visits, including all medications, x-rays and therapy prescribed by your doctor will be charged to you or your insurance company. You will be responsible for all costs that are not paid by your insurance company. This study will not have any added costs to you.

Will you be compensated or paid?

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

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. Since this study does not have any interventions

that are not already considered standard of care, all complications will be treated as complications of the procedure. However, the cost of that treatment will be billed to you or your insurance company.

If you have any medical problems during the study, please contact your study doctor. He or she will explain your treatment options to you or tell you where you can 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 inform 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: **Kern Singh, MD at (312) 243-2339, Frank Phillips, MD at (312) 432-2339, Howard An, MD at (312) 432-2450, Edward Goldberg, MD at (312) 432-2338, or Matthew Colman, MD at (312) 432-2846.** 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 WITNESS:
I observed the signing of this consent document.

_____	_____
Signature of Witness	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this 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
Signature of the Principal Investigator	Date of Signature