

UNIVERSITY OF PENNSYLVANIA

RESEARCH SUBJECT INFORMED CONSENT

Protocol Title:	Postoperative pain after one-visit root canal treatment on teeth with vital pulps: Comparison of two different root filling techniques
Protocol ID:	825494
Institution:	Department of Endodontics School of Dental Medicine University of Pennsylvania 240 S. 40th Street Philadelphia, PA 19104-6033 215-898-4617 (office) 215-573-2148 (fax) Endodontic Clinic 215-898-6062 (main)

Why am I being asked to volunteer?

You are being invited to participate in a research study. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, you will still receive treatment as needed. Please ask the study doctor and/or the research team about this form if you do not understand any of the medical terms.

What is the purpose of this research study?

To determine if two commonly used root canal filling techniques affect post-operative discomfort differently.

How long will I be in the study? How many other people will be in the study?

Your participation in this study will not require any more time than actually needed for your root canal treatment. The quick survey requires minimal effort and should be filled out at 4, 24, and 48 hours after completion of the root canal treatment. You will be provided with a preaddressed and pre-stamped envelope to place in the mail after you complete the survey. We will have about 200 people participating in this study.

Our routine clinic protocol (not related to this study) prescribes follow-up appointments to confirm expected healing with any treatment that we provide. Endodontic Clinic will schedule follow-up appointments upon completion of your treatment.

What are the possible risks or discomforts?

Only the risks or discomforts that can arise during or after any routine root canal treatment procedure apply. There is no known difference in pain between the two techniques we commonly use in the clinic.

What are the possible benefits of the study?

You are not expected to get any benefit from taking part in this research study. Information learned from your participation in this study may benefit others in the future.

What other choices do I have if I do not participate?

You will receive the necessary treatment with the same, standard protocol. General risks, time, effort and fees applicable to the procedure are still the same.

Will I be paid for being in this study?

There will be no compensation provided for taking part in this study.

Will I have to pay for anything?

You and/or your health insurance may be billed for the costs of dental care for your scheduled root canal treatment. These expenses would have happened even if you were not in the study. There is no additional cost for you or your insurance company associated with our study.

What happens if I am injured from being in the study?

This research does not bear any additional risk for injury.

You should contact the Endodontic Department (215)-898 6062 If you have any questions or concerns after your root canal treatment; have any signs of infection such as fever, chills, swelling

or malaise; are in a lot of pain or if the pain after a root canal treatment gets worse instead of better as the days go by.

When is the study over? Can I leave the Study before it ends?

This study is expected to end after a sufficient number of people enroll in the project. Your involvement with the study ends when the survey has been filled out and mailed. If you decide not to participate, you are free to leave the study at any time. Withdrawal will not interfere with your future care. This study may also be stopped at any time by the study Sponsor or Primary Investigator without your consent.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the principal investigator listed in this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

Chart #: _____

Name of Subject (Print)	Signature of Subject	Date
Name of Person Obtaining Consent	Signature	Date