

Are Sham Surgeries Ethical?

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### Introduction

Sham surgeries are known also as surgical placebos. These are used to test the effectiveness of clinical practice procedures, because sham surgery controls prevent false positive results. In an experimental design, half the participants would receive the controlled surgical intervention, and the other half would only have the surgical incisions and not the entire procedure (placebo). The patients are blinded to which group they are in to prevent bias in the results. The assessments in the follow-up appointments would support the hypothesis of whether or not the surgical procedure is effective, and improvement of the patient is not caused by other means. By using the controlled study to test the effectiveness of the surgical procedures, researchers are able to prevent the implementation of useless surgical procedures, where benefits do not outweigh the risk of harmful, and potentially fatal, damages.

Some experts raise the ethical issues of whether or not the patient's rights of beneficence, autonomy, and veracity are being violated. Beneficence may be violated if the patients, in the control group, are placed at risk for complications without any real benefits. Autonomy may be violated if the patient has no control over which group he or she is placed in (clinical trial or sham surgery control). Veracity may be violated if the patients are "blinded" for the study. However, it is explained in the consent form that surgeons will mislead them to believe that they are receiving the actual procedure, whether or not that is true. This raises the question: are sham surgeries ethical? It is the intent of this paper to explore this issue.

### Literature Review

Moseley et al. (2002) tested whether or not arthroscopic surgery is effective in osteoarthritis of the knee. One hundred and eighty participants received an arthroscopic

debridement, arthroscopic lavage, or a placebo (with only surgical incisions). Patients were assessed many times over a 24-month period. The results showed that participants that received the procedures actually had a more difficult time walking and climbing stairs, as opposed to the participants that only received the placebo. This supports the idea that these surgical procedures for patients with osteoarthritis may be more harmful than beneficial, and should probably not be practiced.

The ethical principle beneficence means to promote good (Guido, 2006). This can be argued with patients receiving the placebo surgery, because the patients are being placed at risk without any real benefits. Albin (2005) argued that placing few at risk to benefit a larger group is legitimate. He goes on to state that

harming a few to save many is acceptable when:

- a) Specific group is at risk from a harm causing event(s);
  - b) The setting in which the harms (or risk) are diverted from the many to the few involves only individuals drawn from the larger at risk group;
  - c) Harm (or risk) is diverted/focused between larger and smaller subsets of the originally at risk group, or the diversion/focus occurs between the entirety of the originally at risk group and a subset of the group;
  - d) Harm (or risk) will occur regardless of whether or not the agent diverts/focuses the harm (or risk) from the many to the few; and
  - e) There is a reasonable and legitimate means for allocating risk between the few and many
- (p. 151)

Albin continues to explain how sham surgeries meet these criteria. All surgical interventions pose some risk to patients, satisfying criterion (a). Only patients with a particular medical

condition, for which the surgical intervention is used, can participate, satisfying criteria (b & c). Unless the sham surgery control does not prove the surgical procedure to be ineffective, the procedure in question will be performed, placing those patients at risk, satisfying criterion (d). The trial executes a proper research design, and follows all clinical research standards, satisfying criterion (e).

Horng and Miller (2003) argue that placebo surgeries are ethically justified because they test the safety and efficacy of new clinical procedures. The placebo controlled trial is ethically justified as long as valuable information is to be gained, all risks to the patient are minimized, the placebo control is the only way to test the hypothesis, and procedures are explained to the patient in the consent form that they will be misled during the procedure. According to the authors, the risk has been minimized if placebo surgery is the only way, or poses the least risk of all the options, to measure whether or not the clinical procedure is effective. Sham surgeries are going to have less of a detrimental effect or no risk at all, on the participant when compared to the procedure that is being tested. Miller (2003) contends that in every placebo study the researchers need to perform an ethical analysis. This should include a rationale for the study, risk versus benefit of the study to the participants, and a thorough informed consent that explains to the participants that they will be misled for research purposes.

Margo (2001) presented an opposing view of sham surgeries. He believes patients are often not fully informed prior to surgical interventions, and that often surgeons perform small experiments, by altering usual surgical methods. This is often done without consent. He concluded with the idea that sham surgeries are only acceptable if: the procedure was exhausted in an animal laboratory before being performed in the operating room; the patient signed a consent form explaining everything that is expected to happen during the procedure (including

potential risks); the study has an approved research design with hypothesis, data collection and analysis methods; and the patient's rights are never violated.

Informed consent is an important aspect of the research process. It makes the research trial legitimate. Without an informed consent the trial can not proceed. Albin (2005) explained that morally it is not correct to use sham surgery controls without providing the patient with an informed consent. He refers to informed consent as a "moral safeguard" in experiments.

Informed consent explains the patient's rights during the random clinical trial. Within this consent form the trial is explained. The patient should understand that it is a blinded study, and they do not have a choice of clinical procedure or placebo. However, it is explained to them (the participants) the chances of receiving a placebo, as well as the rationale for the using a placebo in the study. They also must understand that the researchers will mislead them to believe that they are receiving the actual clinical procedure. In order to have reliable documentation of the participants' understanding, the participant should write a statement on the consent form explaining their understanding of the trial, as well as their role. This protects the researchers from being accused of violating the participant's ethical principles.

Hornig and Miller (2003) explained the ethical guidelines for misleading participants in a blind study. The guidelines

require that:

- 1) The misleading is necessary for valid data,
- 2) Subjects are told in the informed consent process that misleading tactics will be used,
- 3) Subjects are not misled about the chance of receiving a sham procedure, and the risks of study participation,

- 4) Debriefing after misleading is made at the end of research participation when the blind is broken (p.128).

Kim, et al. (2005) addressed the ethical opinion of Parkinson disease clinical researchers on placebo surgeries to test the effectiveness of gene transfer for Parkinson disease. The majority (97%) promoted the use of sham surgery controls, citing control efficiencies over other methods. Half the researchers believed that using an unblinded study would lead to false positive results. However, when asked about the invasiveness of the procedure, 90% said that bilateral full burr holes without penetration of the dura is justified.

### Conclusion

Sham surgeries are ethical, as long as guidelines and criteria are followed accordingly. Potential risk is explained to all participants in the informed consent. That risk is equal to or less than the risk of the actual intervention being trialed. The risk must be minimized. Few participants are placed at risk to benefit a larger population. An informed consent explains the study to the participant, as well as their rights. The participant must understand that some autonomy will be lost, as well as veracity, during the trial, but all will be explained in the end.

With the conclusion of this paper, I feel as though my knowledge of sham surgeries has increased. I once thought placebo surgeries were illegal, and now I agree with the idea of performing placebo surgeries when appropriate criteria are met. There should not be a method to create an effective surgical procedure without clinical trial. In order to prevent harm from unnecessary clinical procedures, the procedure needs to be refuted or supported by research. The best method to use is a sham surgery, because it prevents false positive results. By withholding treatment from a few, volunteering participants, we are able to compare the effects of the placebo versus treatment.

## References

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