

Electrical shavers and splashed saline – how blinding has been achieved in surgical placebo-controlled trials

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[Karolina Wartolowska](#)

Karolina Wartolowska explains the importance of blinding and shares the methods used to imitate audio, visual and physical cues to reduce bias during surgical trials

Karolina Wartolowska, lead author of a [review](#) published in F1000Research, explains the creative methods used to make the placebo indistinguishable from surgery treatment.

One morning, your friend and you go to a café and get two identical coffees. Without telling you, a barista gives you a regular coffee and your friend gets a decaf. This means you are blinded to whether your drink contains caffeine or not.

“Non-blinded participants tend to exaggerate the effect or report what they expect to happen.”

Let's say the barista asks you and your friend how alert you feel after your drink and rates how awake you look. If your ratings of alertness are higher than your friend's, this can be interpreted as a result of caffeine.

So, blinding prevents reporting bias because non-blinded participants tend to exaggerate the effect or report what they expect to happen; like feeling more alert after the morning coffee. Blinding also prevents drop-out of participants, because if you are not certain whether your coffee is a decaf you are less likely to pour it away and get a real coffee somewhere else.

Reducing bias

To make the test even more objective, we could give the barista two identical cafetières, without revealing which one contains regular coffee and which one is decaf. In this version of the experiment the person delivering the drink and assessing the results is blinded. They cannot accidentally give away the allocation through their words or behaviour and they cannot “overrate” your alertness because they do not know that you have been given the caffeinated coffee.

In clinical trials, blinding refers to all the steps that are used to make sure that the results of the trial will not

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be affected by the fact that a patient, doctor, researcher or nurse know which treatment any patient has received.

It is becoming important in surgical trials because nowadays, many surgical procedures are performed to reduce pain and improve quality of life. These measures depend on patients’ subjective perception and judgement, and as such, they are prone to bias. Blinding a surgery is challenging because it requires access to the anatomical structure, so it always involves a skin incision or the insertion of a scope.

Indistinguishable

If the procedure requires open surgery, the procedure leaves an obvious mark where the incision has been made, which has to be imitated in the control group. There have been very few placebo-controlled surgical trials that involved full skin incision, like the classic trials on angina in the ‘60s.

“Surgeons and staff in the operating theatre have to imitate the whole procedure, so that the control intervention is as similar as possible to the real surgery.”

Most trials that include a surgical placebo have used a minimally invasive procedure, so that the surgical wound is either very small, e.g., after arthroscopy or laparoscopy, or not visible at all, e.g., after endoscopy or bronchoscopy. In these studies, the “scopy” part, to get access to the anatomical structure, was the same in the surgical and the placebo group, but the main therapeutic procedure involving cutting or burning away of the tissue, was only done in the surgical group.

If patients are under general anaesthesia, blinding is easy because they do not know which procedure was done. Therefore, only the incision wound and the treatment by doctors and nurses after surgery have to be identical to avoid revealing the allocation. But when patients are not fully sedated, blinding is challenging because the surgeons and staff in the operating theatre have to imitate the whole procedure, so that the control intervention is as similar as possible to the real surgery.

Mimicking sensory cues

In existing surgical trials, some ingenious ideas were required to make the real and placebo intervention indistinguishable to preserve the blinding. For example, surgeons imitated the smells by opening the containers of particularly pungent chemicals used during the real surgery. They also created similar sounds by “talking-through” the steps of the procedure, requesting tools or asking nurses to activate the devices.

“Surgeons imitated the smells by opening the containers of particularly pungent chemicals used during the real surgery.”

Surgeons imitated the sensory cues by manipulating the knee as if the actual arthroscopy were performed

or by splashing saline on the knee to simulate an arthroscopic lavage, i.e., washing inside of the joint. In one trial, surgeons used a mechanized shaver (without the blade) pushing it firmly against the patella (kneecap) to simulate the sensations the patient would experience during the surgery.

In some trials, there have also been attempts to blind surgeons, for example, in two studies of sleep apnea, a palatal implant delivery system was designed by the manufacturer to either contain the implant or not, meaning that the surgeon would not know whether they were administering the real treatment or the placebo.

Footnote: Placebo-controlled trials on caffeine

If you are curious about placebo-controlled trials on caffeinated and decaf coffee you may want to read Kirsch and Weixel’s paper of 1988 “Double-blind versus deceptive administration of a placebo”. (Behav. Neurosci. 102, 319-323).

And you might not know that some coffee chains use [blinding of customers](#) to test new products – there are unmarked coffee shops in which new products are tested on [unsuspecting customers](#).

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