Physicians and surgeons have a long history of differences. Surgeons descended from barber-surgeons and even today are called "Mister" in the United Kingdom. Physicians practicing medicine seem to have descended from the alchemists and are often felt to be more thoughtful and reflective while surgeons are seen more as doers.

A thought provoking systematic review in the British Medical Journal, "Use of Placebo Controls in the evaluation of surgery," examines one of the ways that differences persist. For example, a new therapy involving a medication requires the approval of the FDA, and that requires evidence that the new drug is at least "non-inferior" to what is already available. Not so for a new surgical technique or device. For my surgical brethren, all we need is a good idea and our "can do" attitude takes over, and we try out a new technique, instrument or operation. Once the novel surgical "treatment" is being used, then we can do those studies, "non-inferior" may be more our opinion than a statistical finding.

Surgeons “don’t let the skin come between them and the problem,” was an oft repeated maxim in the era of my training. Now we are far-less invasive; a long incision has been replaced with two or three one-inch incisions, a bypass replaced with an angioplasty and stent inserted through a needle puncture. The article’s first new thought, at least for me, was that the definition of surgery was “any procedure that both changes the anatomy and requires a skin incision or use of endoscopic techniques.” While I resist being lumped in with the gastroenterologists and cardiologists, I at least recognize that it may be time to consider surgical care as “changing anatomy,” with the degree of invasiveness no longer being an apt descriptor. [1]

As you might expect, the literature is not chock full of studies comparing a surgical procedure to placebo. While the study of a drug versus placebo is standard practice, the picture changes
radically when the placebo is a sham operation [2] involving incisions and anesthesia. (We will return to this ethical issue in a moment.) Of about 3000 articles, 53 full-text articles were selected. They represented randomized controlled studies, with both an active intervention and a placebo arm involving a sham procedure. The authors defined a surgical outcome based on three elements:

- The critical surgical component – the anatomic changes felt to result in a therapeutic effect
- Placebo component – the patient’s expectations
- Non-specific effects – changes in the natural history of an illness that might impact the outcome, the experience of being in a hospital, interactions with staff - the multitude of other factors.

The authors looked at both the improvement in outcomes for surgical patients and the magnitude of the difference in that improvement compared to the placebo arm. In their opinion, this was the additional benefit of surgery over placebo alone.

- Most trials investigated non-life threatening conditions; 43% involved endoscopy, 25% involved implanting exogenous material or tissue
- Most trials were small, with a median size of 60 patients
- Most trials reported subjective outcomes such as pain relief, improvement in symptoms or quality of life. Forty-two percent had objective outcome measures
- Seventy-two percent showed improvements in both the surgical and placebo arms of the study. Thirteen percent showed improvement only in the surgical arm. The studies’ authors reported improvement from surgery in 49% and no difference from placebo in the remaining 51% of the systematic review.
- Forty-five percent of the studies showed “no statistically significant benefit of the active surgical intervention over the placebo,” and 23% showed a significant superiority of surgery over placebo, with an additional 20% showing surgical superiority for some of the reported outcome measures.

The authors concluded that surgery was no better than placebo in some instances, that the placebo effect was as real for surgeons as for the physicians prescribing medications. They argue that randomized controlled trials with patients undergoing surgery or receiving a placebo, in this case, a sham surgery can demonstrate surgery’s actual efficacy and is a useful tool in identifying which treatments are efficacious and should be pursued and which should no longer be practiced.

Now to the ethical considerations, beginning with do no harm. Harm, in these type of clinical trials, can be considered either complications from surgery or lack of improvement. Now when patients participate in clinical trials with a placebo arm, lack of improvement is a distinct possibility, which is addressed in the informed consent. So, the specific ethical concerns of using a surgical placebo are about complications attributed to the sham procedure. In reviewing those 53 papers, the authors noted the following concerning surgical complications.

- Fifty-one percent of the studies reported serious adverse effects. In those studies, 63% were adverse effects in the surgical group.
- In the remaining 37%, the harms in the placebo arm were most often related to surgical
incisions or implants.

- The authors believe that surgical trials are warranted when the surgical benefit is unclear or when standardized treatment is not available. They do caution that “the balance between risks and benefits in surgical placebo controlled randomized clinical trials is different from that in drug trials.”

As with any ethical dilemma, I am ambivalent here. Since we are in unchartered territory it is difficult to know how we should proceed. This depends on a variety of factors, and (not surprisingly) the authors found no studies that used surgical placebos in the evaluation of life-saving procedures. Requiring procedures to be evaluated as we do life-saving or extending drugs would help us to avoid unnecessary, ineffective surgical intervention. But it might, unfortunately, become a series of non-inferiority claims. And regulation will certainly constrain if not stifle the current innovative atmosphere surrounding procedural therapies – an environment that has taken us from large surgical incisions, and long hospital and recovery stay, to punctures and endoscopy and outpatient care in a one clinical lifetime. [3]

[1] On the other hand, I will resist to the end of my days being called an interventionalist or proceduralist, I feel more at home being a surgeon.

[2] A surgical incision was made but no procedure performed, or a patient underwent anesthesia and had an endoscope placed without any further intervention.

[3] Repair of an abdominal aortic aneurysm has gone from a 3-4 hour procedure involving an abdominal incision about 18 inches long, 2 or 3 days stay in ICU, a week in the hospital to a procedure performed using two needle punctures, and most frequently an overnight stay (Medicare rules mandate the overnight stay. Otherwise we could easily begin to see out-patient care)