

# Surgery, the ultimate placebo

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Angina

Parkinson's disease

Migraine

Knee pain




# Spine surgery

Injection therapy for pain

# Spine steroids?

- No benefit over placebo
- Risks
- Costs

Perspectives 

## Time to reconsider steroid injections in the spine?

Steroid injections to the spine provide no advantage over placebo, but do carry risks of harm

**G**lucocorticoid (often simply called “steroid”) injections into the spine, a procedure frequently performed by specialist radiologists using imaging for localisation, are increasingly being used to treat non-specific low back pain or leg (radicular) pain due to disc herniation or spinal stenosis. A report from the United States shows a sixfold increase in Medicare expenditure for epidural steroid

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show any significant benefits of steroid over placebo (saline or local anaesthetic) injections indicates that the steroids themselves have no direct therapeutic effect. As well as the placebo effect, other factors such as regression to the mean and a favourable natural history may also explain the observed improvements.

Given the lack of evidence for a clinically important benefit over placebo, a small but not insignificant risk of harm, and the rising costs associated with their increasing use, is there a justification for continued use of spinal



Spinal cord stimulators

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(onlinelibrary.wiley.com) DOI: 10.1111/ner.12027

# **Analgesic Efficacy of High-Frequency Spinal Cord Stimulation: A Randomized Double-Blind Placebo-Controlled Study**

**Christophe Perruchoud, MD\*; Sam Eldabe, MBChB, FRCA, FFPMRCA<sup>†</sup>;**

HFSCS was equivalent to sham for the primary outcome (improvement of PGIC) as well as for both the secondary outcomes (VAS and EQ-5D index)

**Systematic Review**



# **Effectiveness of Spinal Cord Stimulation in Chronic Spinal Pain: A Systematic Review**

Jay Grider, DO, PhD<sup>1</sup>, Laxmaiah Manchikanti, MD<sup>2</sup>, Alexios Carayannopoulos, DO, MPH<sup>3</sup>, Manohar Lal Sharma, MD, FRCA, FFPMRCA<sup>4</sup>, Carl C. Balog, MD<sup>5</sup>, Michael E. Harned, MD<sup>6</sup>, Vahid Grami, MD, MPH<sup>7</sup>, Rafael Justiz, MD<sup>8</sup>, Kent Nouri, MD<sup>9</sup>, Salim M. Hayek, MD, PhD<sup>10</sup>, Ricardo Vallejo, MD, PhD<sup>11</sup>, and Paul J. Christo, MD<sup>12</sup>

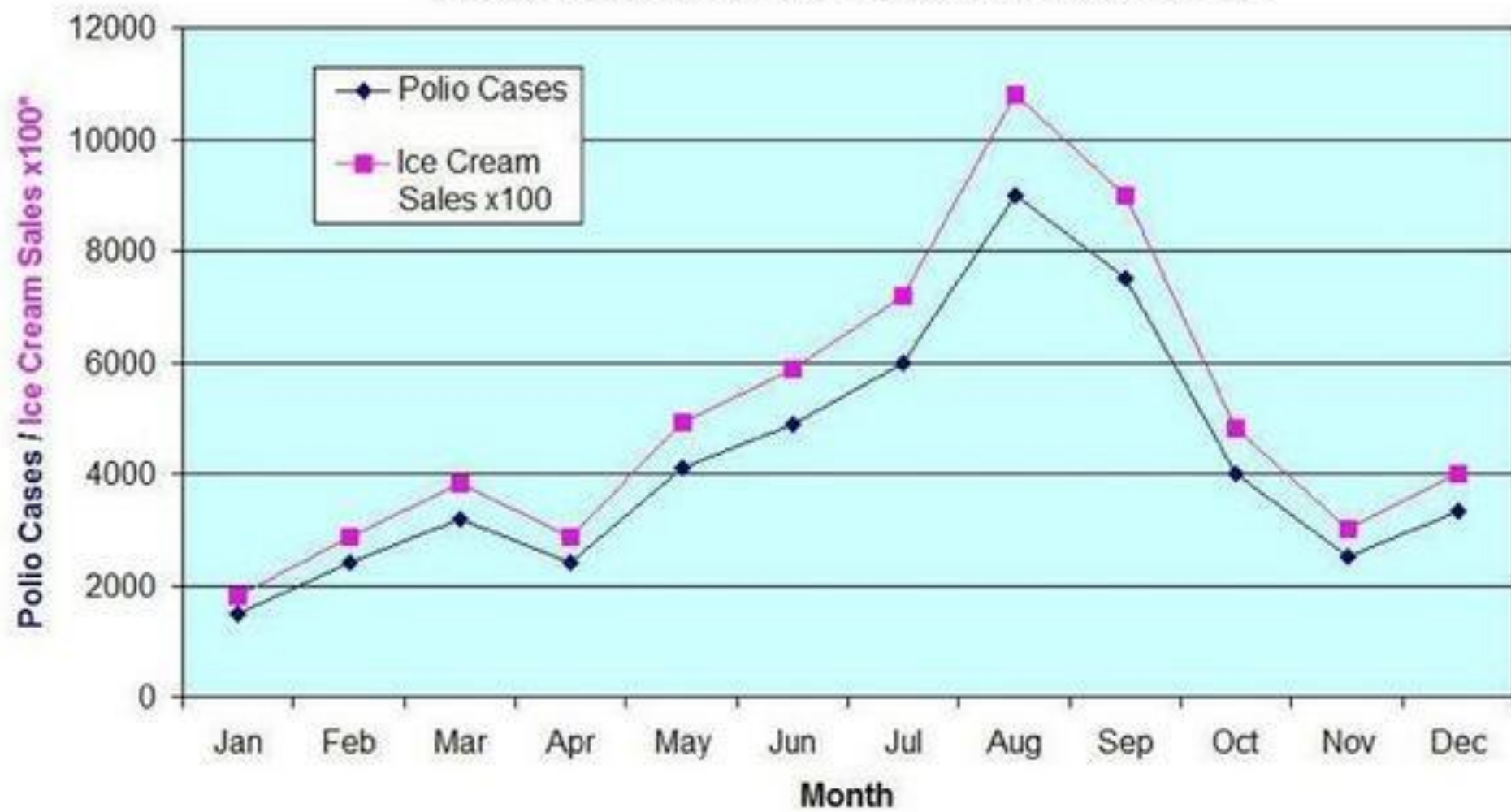
The evidence for high frequency stimulation based on one high quality RCT is Level II to III

Table 2. *Methodological assessment of randomized clinical trials evaluating spinal cord stimulation in chronic spinal pain.*

	<b>Kapural et al (38,39)</b>	<b>North et al (13)</b>	<b>Kumar et al (18,86)</b>	<b>Schultz et al (77)</b>	<b>Perruchoud et al (78)</b>	<b>Schu et al (79)</b>
Randomization adequate	Y	Y	Y	Y	Y	Y
Concealed treatment allocation	U	Y	Y	N	N	Y
Patient blinded	Y	N	N	N	N	N
Care provider blinded	N	N	N	N	N	N
Outcome assessor blinded	N	N	N	N	N	N
Drop-out rate described	Y	Y	Y	Y	Y	Y
All randomized participants analyzed in the group	Y	N	Y	Y	Y	Y
Reports of the study free of suggestion of selective outcome reporting	Y	Y	Y	N	Y	Y
Groups similar at baseline regarding most important prognostic indicators	Y	U	Y	Y	Y	Y
Co-intervention avoided or similar in all groups	Y	Y	Y	Y	U	Y
Compliance acceptable in all groups	Y	Y	Y	Y	Y	Y
Time of outcome assessment in all groups similar	Y	Y	Y	Y	Y	Y
SCORE	9/12	7/12	9/12	7/12	7/12	9/12

# Explaining perceived effectiveness

## Polio Rates / Ice Cream Sales 1949

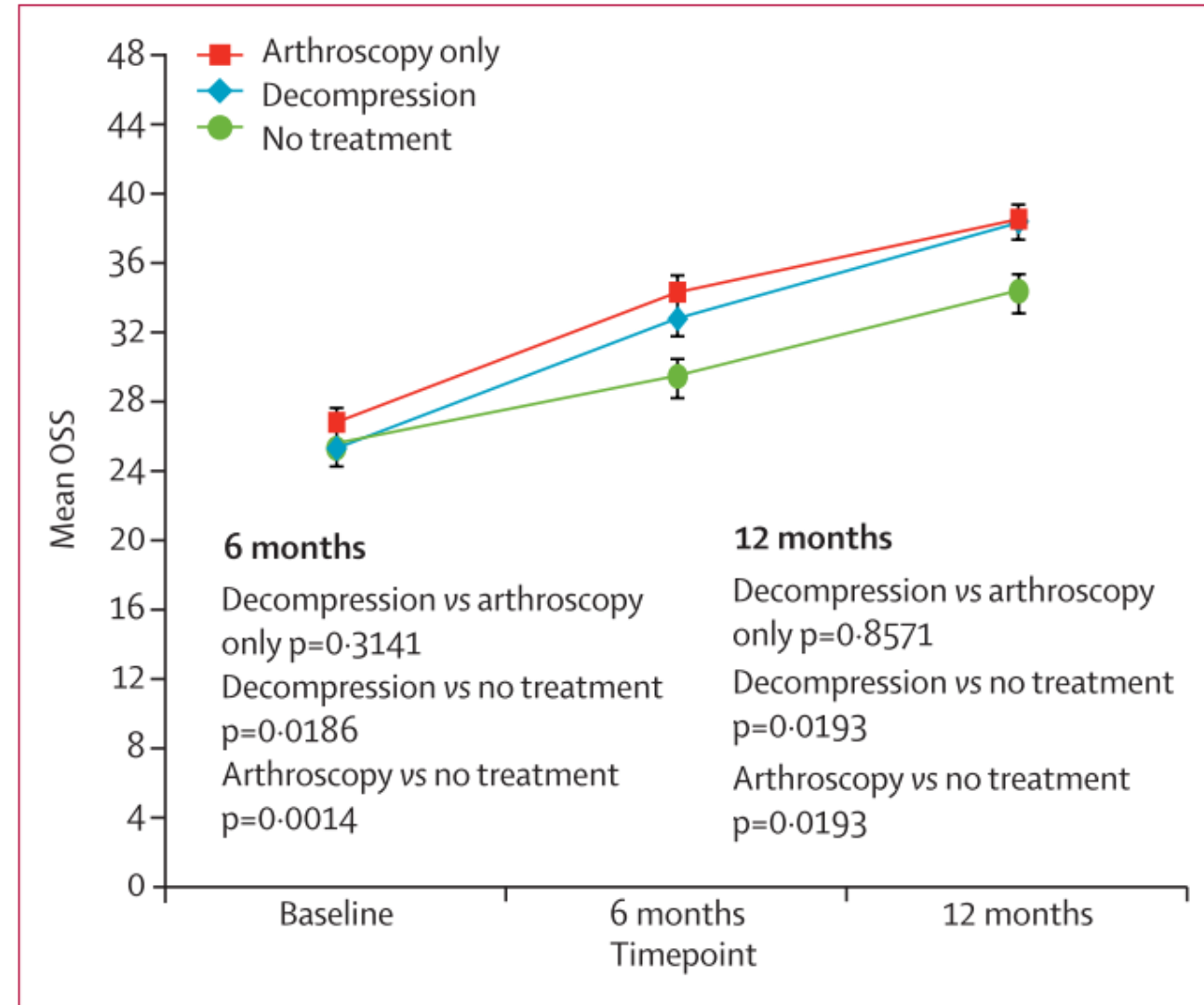


# Improvement not due to the surgery

- Post hoc ergo propter hoc
  - Natural history
  - Regression to the mean
  - Concomitant treatment

# Improvement not due to the surgery

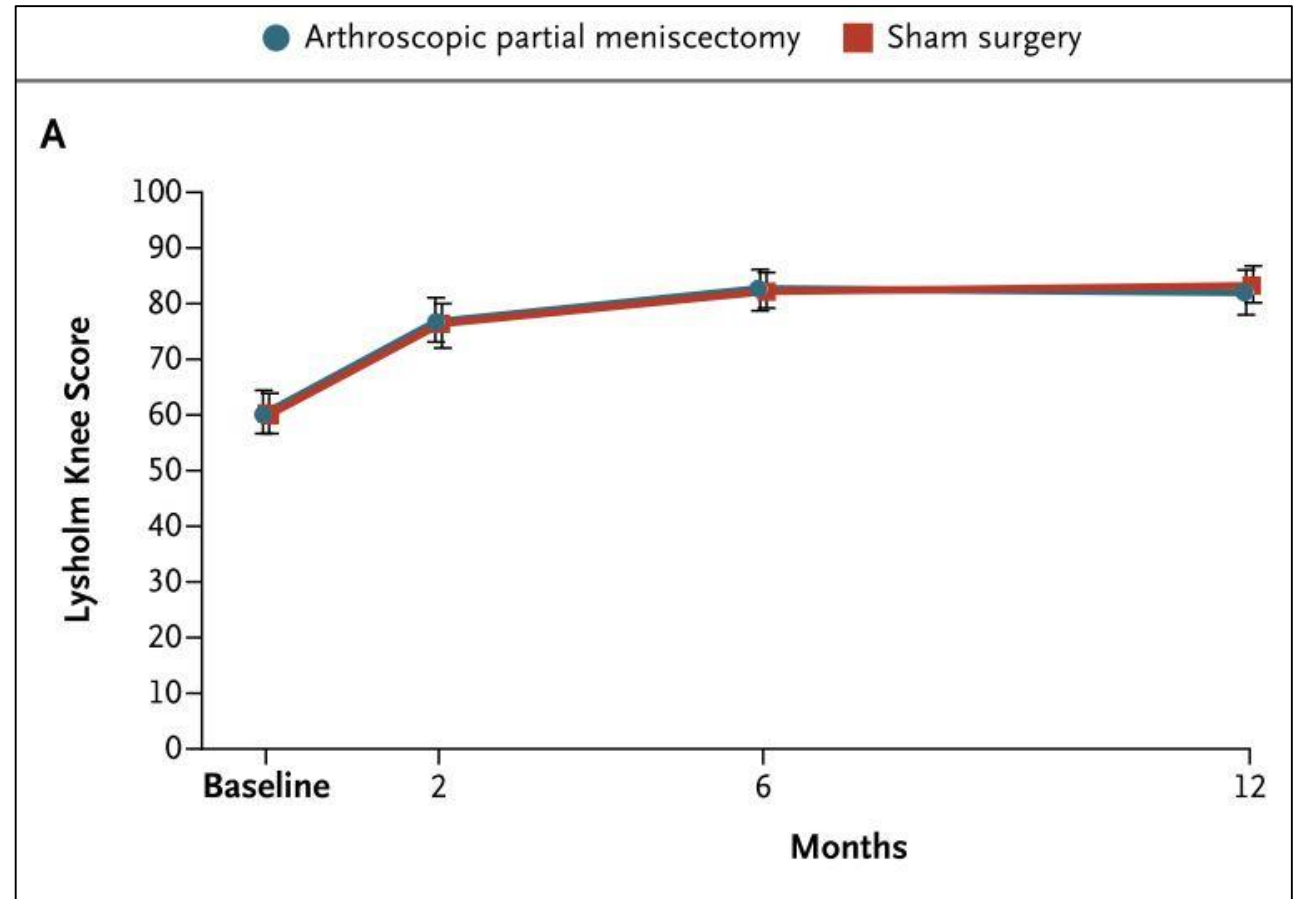
- Post hoc ergo propter hoc
- Natural history (Cochrane)
- Regression to the mean
- Concomitant treatment





# Improvement not due to the surgery

- Post hoc ergo propter hoc
  - Natural history
  - Regression to the mean
  - Concomitant treatment



# Improvement not due to the surgery

- Post hoc ergo propter hoc

• Natural history

• Regression to

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**Osteogenic Protein-1 (Bone Morphogenetic Protein-7) in the Treatment of Tibial Nonunions : A Prospective, Randomized Clinical Trial Comparing rhOP-1 with Fresh Bone Autograft**

Gary E. Friedlaender, Clayton R. Perry, J. Dean Cole, Stephen D. Cook, George Cierny, George F. Muschler, Gregory A. Zych, Jason H. Calhoun, Amy J. LaForte and Samuel Yin  
*J Bone Joint Surg Am.* 2001;83:151.

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- Concomitant treatment

# Perceived effectiveness: surgeon vs patient

## Discordance Between Patient and Surgeon Satisfaction After Total Joint Arthroplasty

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Justine M. Naylor BAppSc(Phty), PhD<sup>a,c</sup>, Sam Adie MBBS, MSpMed, MMed(Clin Epi)<sup>a,c</sup>,  
Rajat Mittal MBBS, MS<sup>a,c</sup>, Alan T. Dao MBBS<sup>c</sup>

## Predictors of patient and surgeon satisfaction after orthopaedic trauma

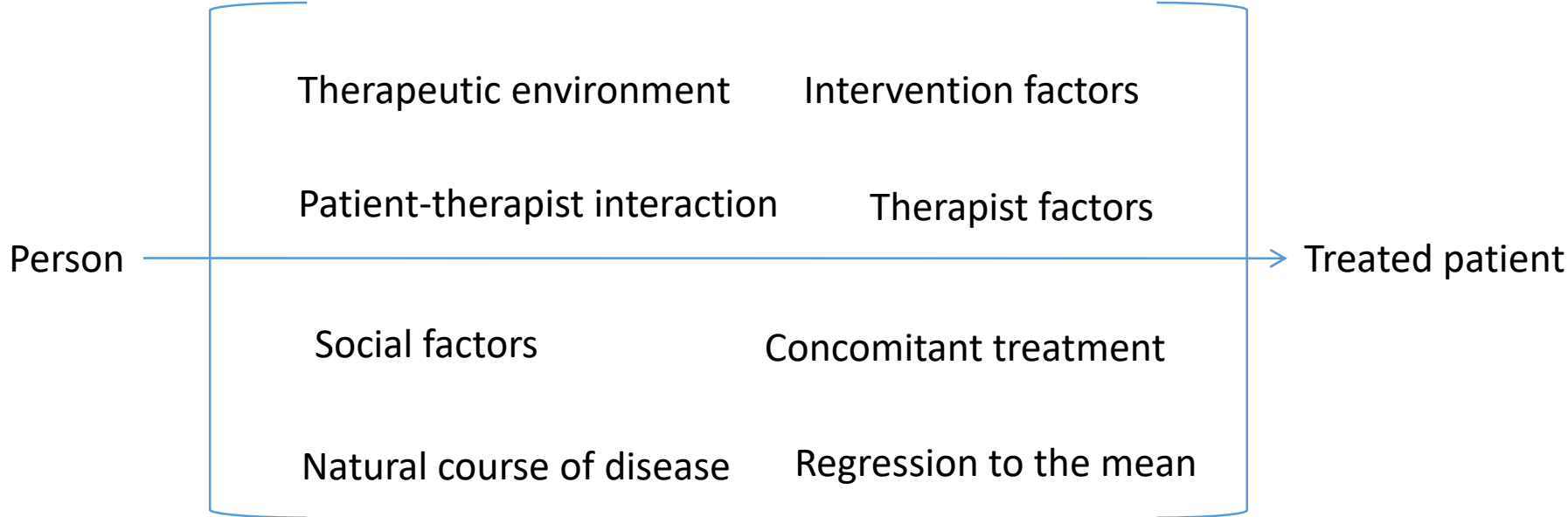
Ian A. Harris<sup>a,b,\*</sup>, Alan T.T. Dao<sup>b,1</sup>, Jane M. Young<sup>c</sup>, Michael J. Solomon<sup>c</sup>, Bin B. Jalaludin<sup>d,2</sup>

**JAMA Internal Medicine | Review | LESS IS MORE**

# Clinicians' Expectations of the Benefits and Harms of Treatments, Screening, and Tests A Systematic Review

Tammy C. Hoffmann, PhD; Chris Del Mar, MD, FRACGP

# Therapeutic envelope



# Intervention: the placebo pill

Colour

Size

Cost

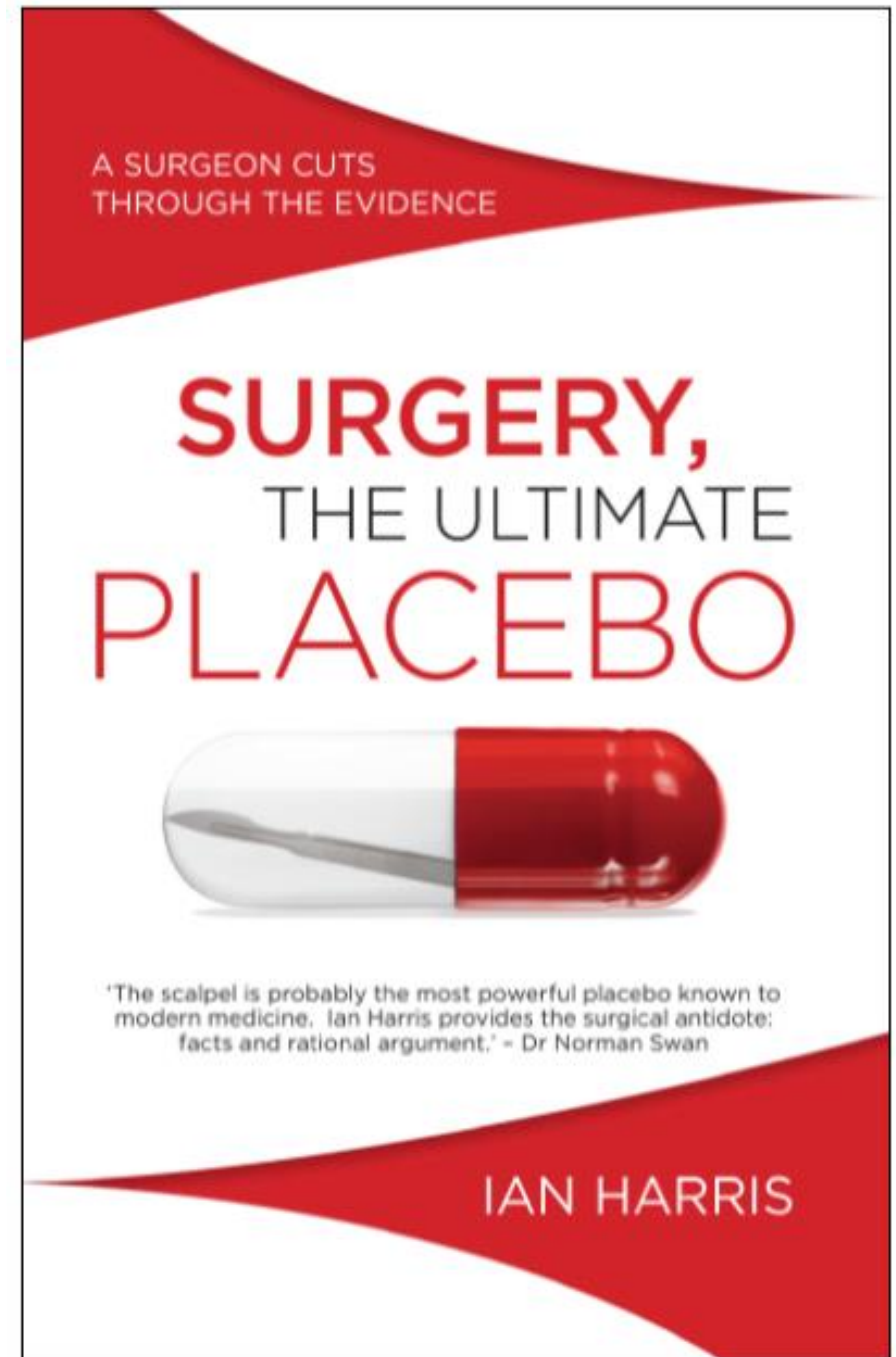
Number

“Active” placebo

# Building the ideal placebo

- Painful interventions and “procedures”
- Devices, make it look ‘scientific’
- Confident, enthusiastic, authoritative, qualified provider

# The ultimate placebo





# Why do we still operate

- Belief in effectiveness
- Patient demand?
- “Failure of non-operative treatment”
- Lack of alternatives
- So it’s a placebo – who cares?

‘Physicians are not prepared to discard therapies validated by both **tradition** and their own **experience** on account of someone else’s numbers’

*American Journal of Medical Sciences, 1836*

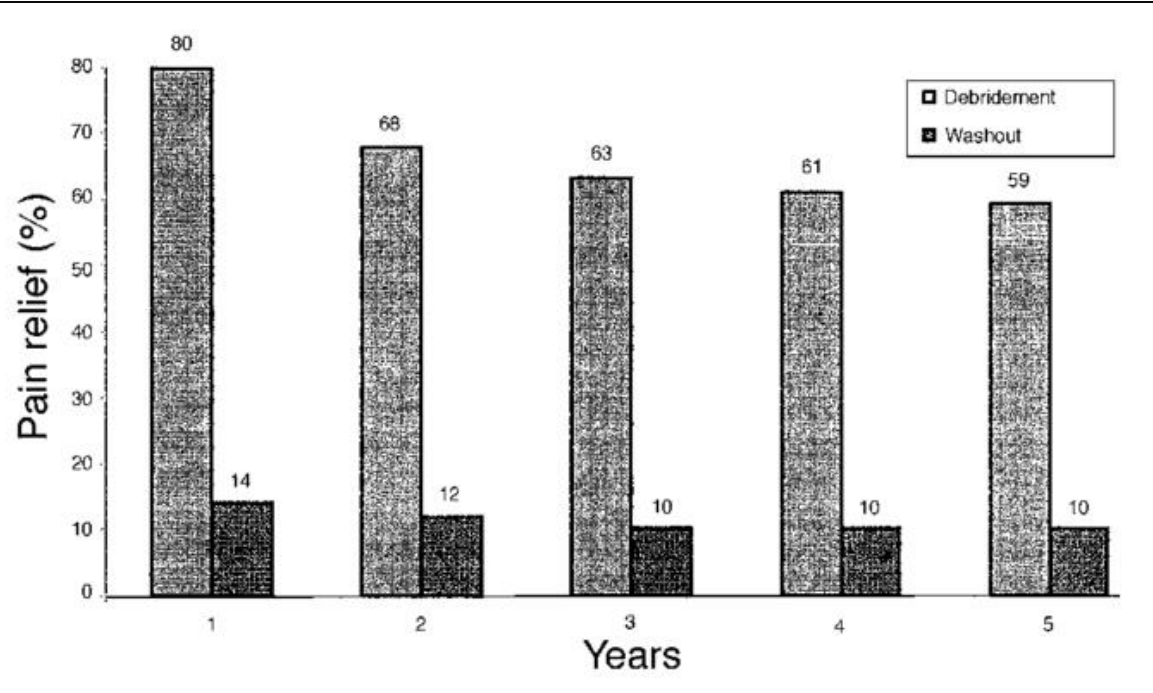
# Determining effectiveness

- What surgery historically relies on
  - Biologically plausible mechanism
  - Laboratory evidence
  - Observational studies
- What should be used to determine effectiveness
  - The method with the least error

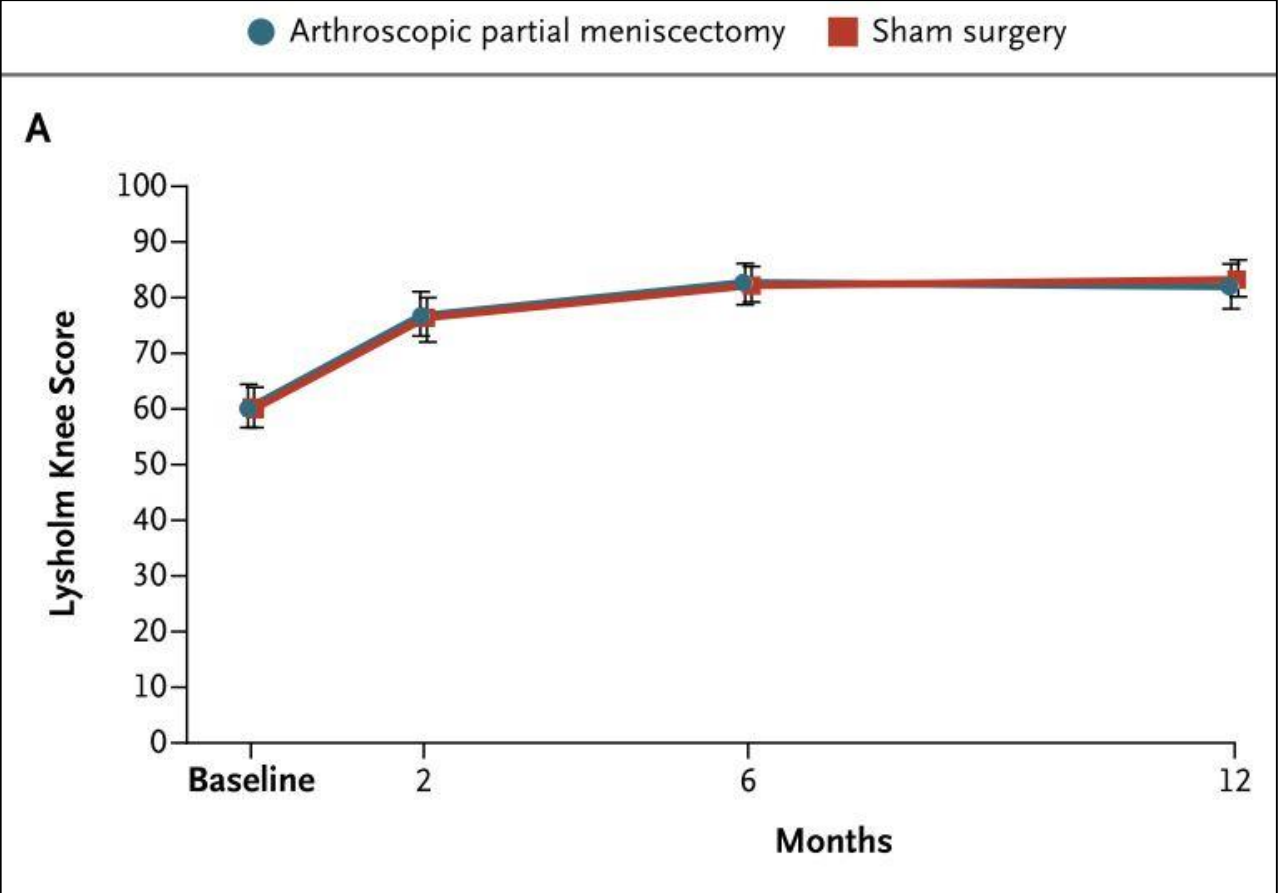
# Reducing error in estimating the truth

- Reduce random error
- Reduce systematic error (bias)
  - Reducing known bias
  - Reducing unknown bias
- RCTs with low 'risk of bias'

# Knee arthroscopy



Hubbard 1995



Sihvonen 2013

# One possible solution

- Treat procedures like drugs
  - Cover treatment, only if being *adequately evaluated*
- Win-win
  - Uncertainty reduced for all
  - Value provided

# Inadequate evaluation

- A database
- A case series
- A non-randomised trial
- An unblinded trial

# So what's next?

- Better evidence is being generated, e.g. shoulder surgery
- Better evidence needs to be demanded



# Summary

- Perceived effectiveness of surgery greater than true effectiveness
- Blinded trials offer the least biased measure of effectiveness
- Most surgical procedures have not been subjected to blinded trials