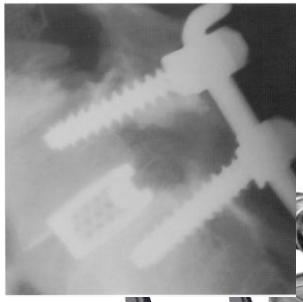
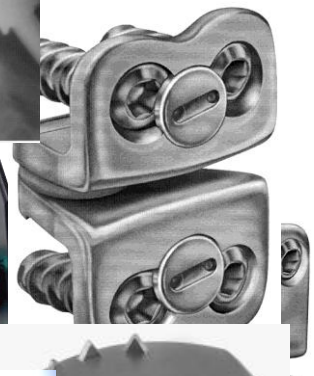
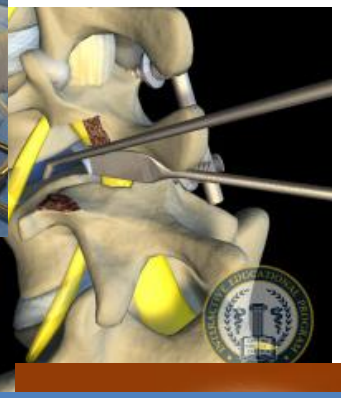
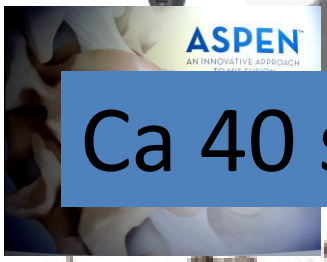
Kirurgiske intervensjoner ved nakke og ryggsykdommer
Erfaringer med norske multisenter studier

Øystein P. Nygaard
Senter for spinale lidelser/
Nevrokirurgisk avdeling
St. Olavs Hospital/NTNU

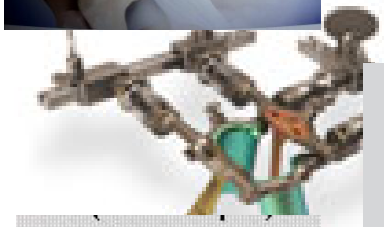
Toys for boys

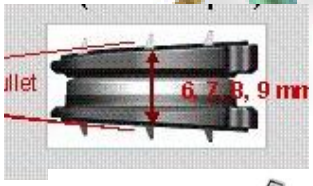


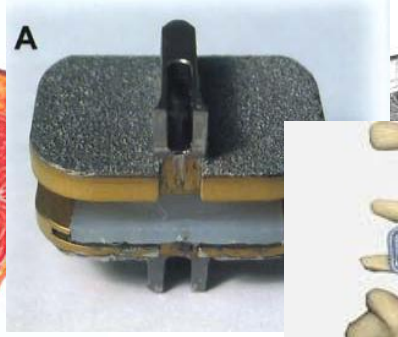


Ca 40 skiveproteser på markedet pr 2011

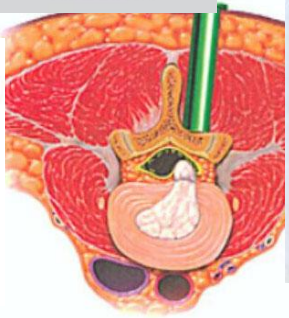












SPINE Volume 34, Number 5, pp 423–430

Clinical Research

Is the Spine Field a Mine Field?

Eugene J. Carragee, MD,* Richard A. Deyo, MD, MPH,† Francisco M. Kovacs, MD, PhD,‡§
Wilco C. Peul, MD, PhD,¶ Jon D. Lurie, MD, MS,‖ Gerard Urrútia, MD,**
Terry P. Corbin, BS,††‡‡ and Mark L. Schoene, BS§§

Table 2. Myths and Realities About Medical Device Evaluation and Regulation

Myth	
New device must be better than an old one to be approved	No comparison with competing devices is r equally effective, more effective, or less e
Studies done for approval are likely to uncover all important side effects	For new drugs, 50% have important side eff marketing. No data available for devices, likelihood of a problem of at least similar
Device approval is similar to drugs	Most devices (over 98%) approved on a cla already on the market. This may seem pa newness and innovation. Evaluation focus than clinical efficacy. Unlike drugs, no ra judged to be the most innovative or risky.
Devices are approved only if they offer good value for money	FDA is prohibited from considering cost or
Off-label uses of devices are well-evaluated	Off-label use of many devices is common ar established because there is no incentive indication.
Ineffective devices are recalled	Devices are recalled only for safety problem efficacy.
Surgical procedures are regulated by FDA	No procedures are regulated by the FDA; o

Financial Ties Are Cited as Issue in Spine Study

By REED ABELSON
Published: January 30, 2008

Some of the nation's most prominent spine surgeons hailed it as a medical breakthrough.

In a study of nearly 240 patients with lower back pain, the doctors said that the Prodisc, an artificial spinal disk, had worked much better than conventional surgery in which patients' vertebrae were fused.

"As a surgeon, it is gratifying to see patients recover

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PRINT
REPRINTS
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More Articles in Business »

Registerdata vs randomiserte studier

	RCT's	Cohort studies
Question	Efficacy—can the intervention work?	Effectiveness—does the intervention work when used in normal practice?
Setting	Well resourced, "ideal" setting	Normal practice
Participants	Highly selected.	Little or no selection beyond the clinical indication of interest
Intervention	Strictly enforced and adherence is monitored closely	Applied flexibly as it would be in normal practice
Generalisability (external validity)	Low	High
Relevance to practice	Moderate	High

Zwarenstein M et al. BMJ 2008;337:a2390

Norsk spinalkirurgi

- Ortopeder og nevrokirurger
- 5500 operasjoner/år (degenerative tilstander)
- 40 sykehus
- Randomiserte studier: multisenterstudier

Kirurgiske intervensjonsstudier

- Multisenter, randomiserte, (enkeltblindet)
- Utprøving av ny teknologi
- Enighet i fagmiljøet om tidlig utprøving
- Riktig timing!

Norwegian Multicenter Study

N W E S

CERVICAL DISC REPLACEMENT

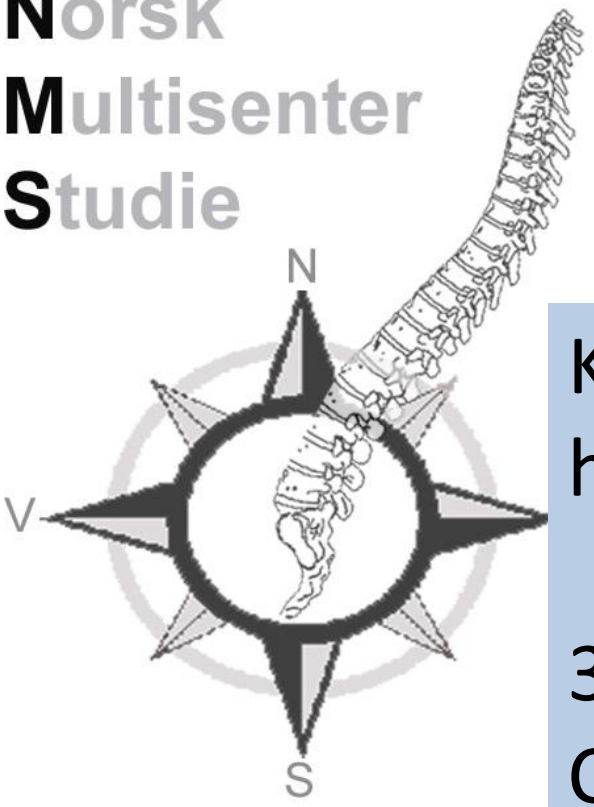
PROSTHESIS VS CAGE

LUMBAL SPINAL STENOSE STUDIEN

En nasjonal multisenterstudie

Norsk multisenterstudie
Skiveprotese vs tverrfaglig ryggrehab

Norsk
Multisenter
Studie



Klinikk, biomekanikk og helseøkonomi

3 stipendiater:
Christian Hellum
Lars Gunnar Johnsen
Linda Berg

Studieledelse:
Jens Ivar Brox
Stipendiater: C
Lars Gunnar Johnsen NTNU

Skeletal Radiol (2012) 41:1547–1557
DOI 10.1007/s00256-012-1394-5

Spine Publish Ahead of Print
DOI: 10.1097/BRS.0b013e318263cc46

Adjacent level degeneration and facet arthropathy after disc prosthesis

Eur Spine J (2012) 21:681–690
DOI 10.1007/s00586-011-2145-3

ORIGINAL ARTICLE

Predictors of outcome after surgery with disc prosthesis and rehabilitation in patients with chronic low back pain and degenerative disc: 2-year follow-up

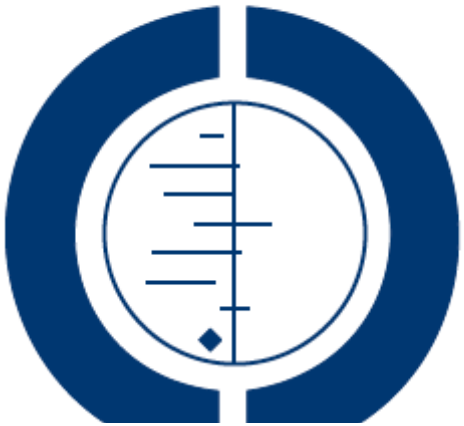
Christian Hellum · Lars Gunnar Johnsen · Øyvind Gjertsen · Linda Berg · Gesche Neckelmann · Oliver Grundnes · Ivar Rossvoll · Jan Sture Skouen · Jens Ivar Brox · Kjersti Storheim · The Norwegian Spine Study Group

BMJ

RESEARCH

Total disc replacement for chronic back pain in the presence of disc degeneration (Review)

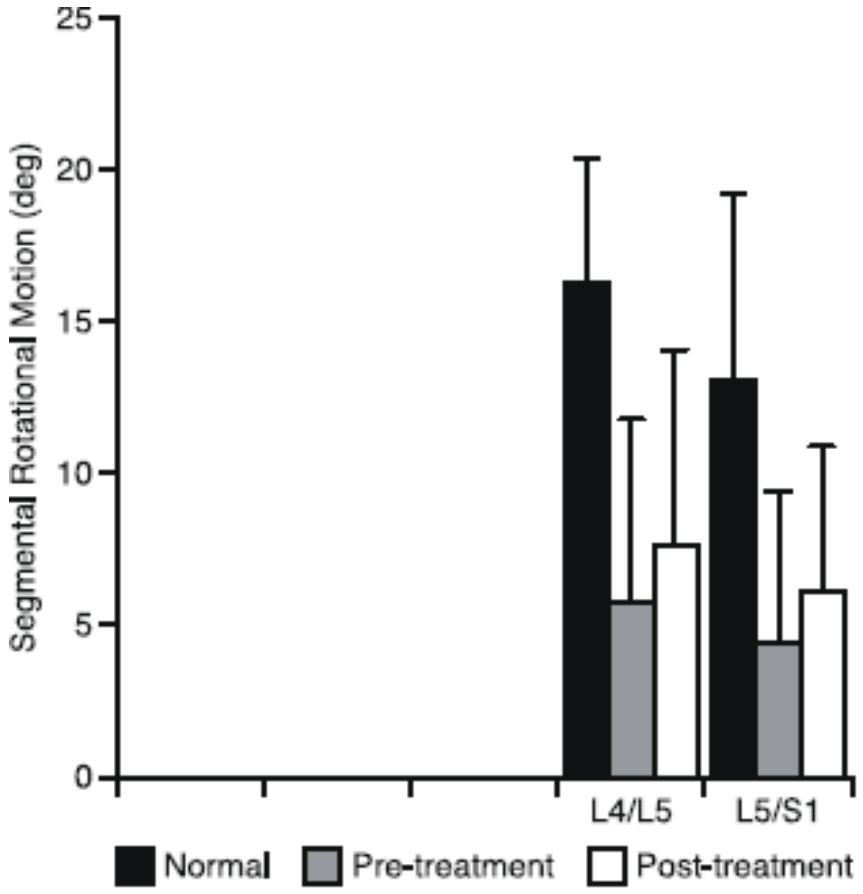
Jacobs W, Van der Gaag NA, Tuschel A, de Kleuver M, Peul W, Verbout AJ, Oner FC



We identified seven randomised trials-involving a total of 1474 patients. Only one study compared total disc replacement with nonsurgical treatment, suggesting that surgery resulted in slightly better outcomes than intensive rehabilitation. But this did not translate into a *clinically significant* advantage that would make a major difference in patients' lives.

orthopaedics), Anne Keller, Berit Johannessen, Anna Maria Eriksdotter (department of physical medicine and rehabilitation).

Biomekanikk



The movement is not restored!

Norges største avis

Aftenposten

Tirsdag
13. november 2012
Uke 46 Nr. 345
153. årgang
kr 25

KULTUR • SIDE 48–49

Statsansatte tror de skriver godt

Offentlig språk er ofte tungt og vanskelig, synes mange. Men byråkratene er slett ikke misfornøyd med seg selv.

BIL • ØKONOMI • SIDE 30–31

Suksessbiler i ny innpakning

Mange av de mest populære bilmodellene dukker nå opp i nye versjoner, inkludert syvende generasjon VW Golf.

NYHETER • DEL 1 • SIDE 6–7

Vil sette en grense for hva pasienters liv er verd

Hvor mye penger skal samfunnet betale for å holde en pasient i live? Nå foreslås en maksimalgrense på omkring 500 000 kroner pr. leveår.

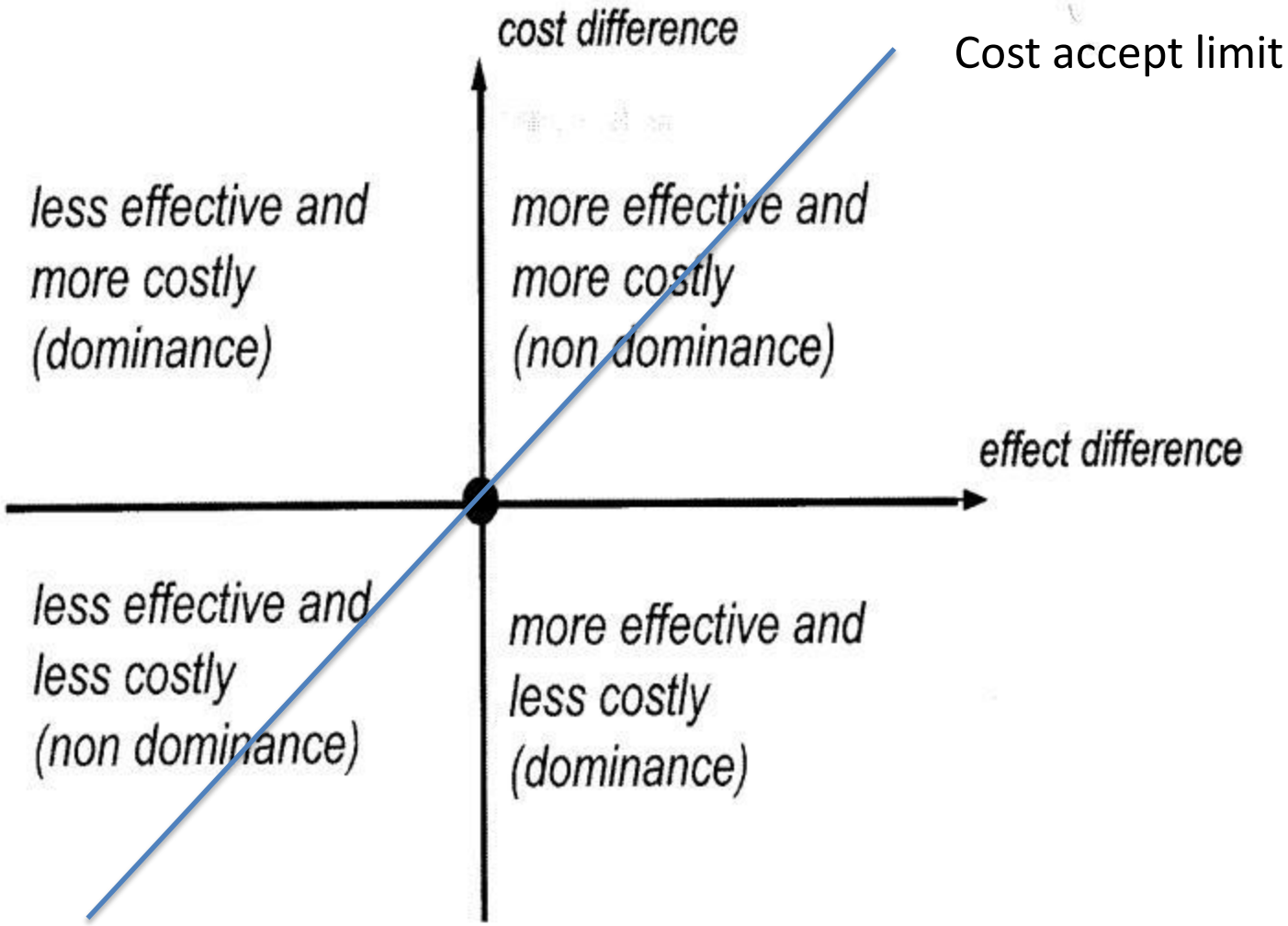
500000 pr QUALY´s?

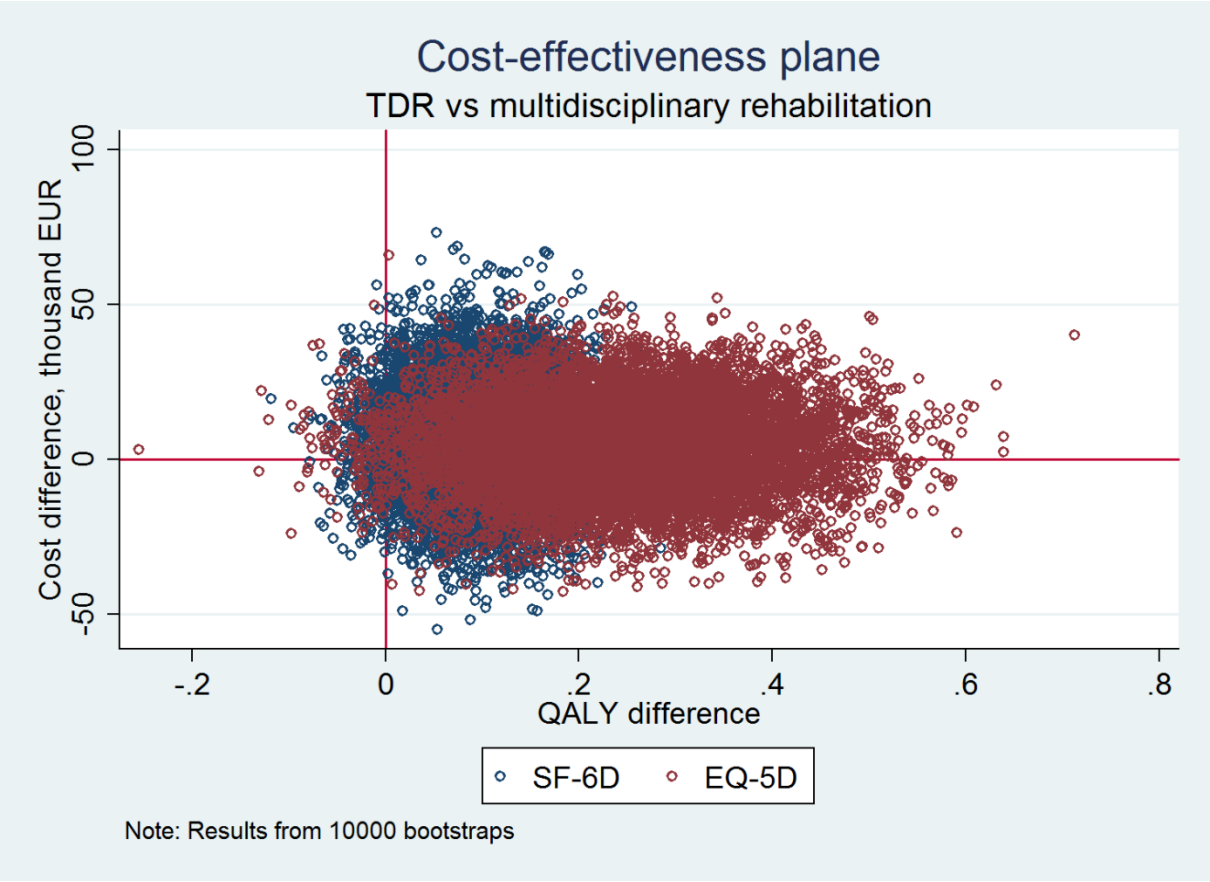
Helseøkonomi
(Lars Gunnar Johnsen)

- Kost-nytte analyse:
  - QALY (kvalitetsjusterte leveår) som hovedeffektvariabel
  - Kostnader for sykehusbehandling, trygdeutgifter og pasientutgifter som økonomisk variabel
- Kost-aksept kurver:
  - Sannsynlighet for at en intervensjon er mer kostnadseffektiv enn en annen gitt beslutningstagers betalingsvilje (”Willingness to pay”)

$$\text{ICER} = \frac{\text{Kostnad kirurgi - Kostnad rehab}}{\text{QUALY kirurgi - QUALY rehab}}$$

Helseøkonomi

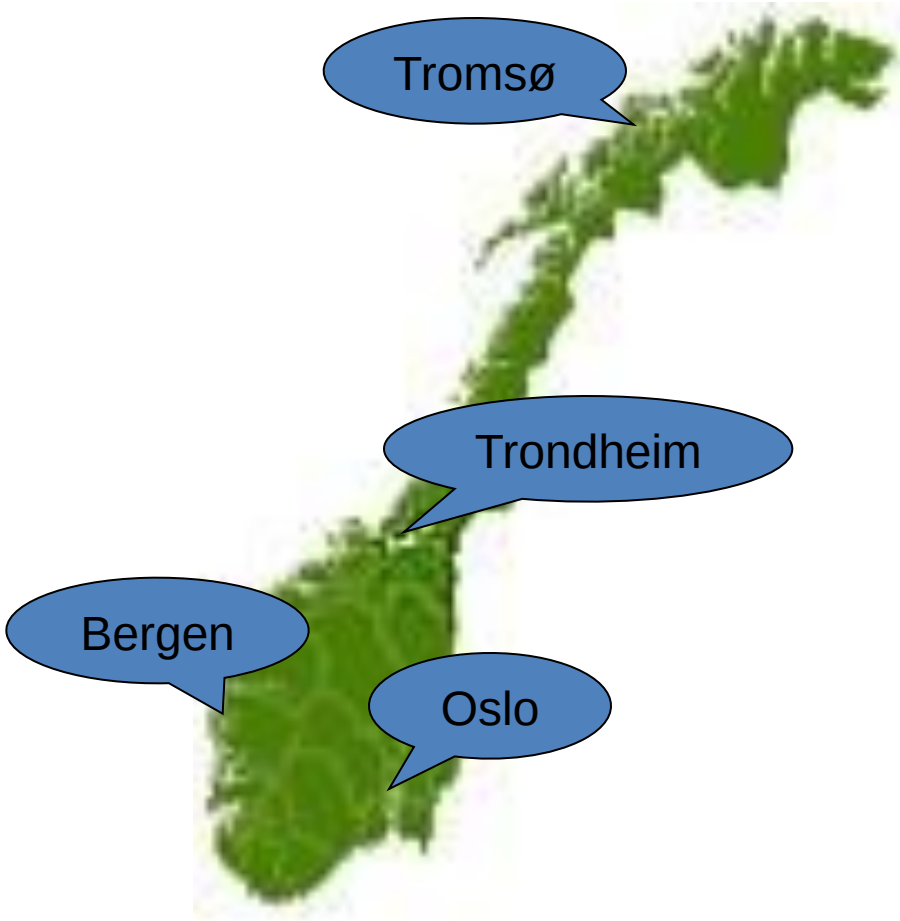



Cost-effectiveness plane
TDR vs multidisciplinary rehabilitation
Cost difference, thousand EUR
100
50
0
-50
-.2
0
.2
.4
.6
.8
QALY difference
SF-6D
EQ-5D
Note: Results from 10000 bootstraps

Nasjonal multisenterstudie

CERVICAL DISC REPLACEMENT

PROSTHESIS VS CAGE



- Cervikal skiveprotese vs avstivning med bur
  - Enkeltblindet
  - Klinikk, biomekanikk, helseøkonomi

3 Stipendiater

Jarle Sundseth
Oddrun Fredriksli
Clemens Weber

Nasjonal multisenterstudie

LUMBAL
SPINAL
STENOSE
STUDIEN

En nasjonal multisenterstudie

Stipendiat
Greger Lønne

Norwegian Multicenter Study

Multisentertudier

LUMBAL SPINAL STENOSE STUDIEN

En nasjonal multisenterstudie

- Utgangspunkt
  - Enighet om behov for ny kunnskap
  - Grundig protokoll
  - Ønske om å drive god klinisk forskning

CERVICAL DISC REPLACEMENT

PROSTHESIS VS CAGE

Multisenter studier

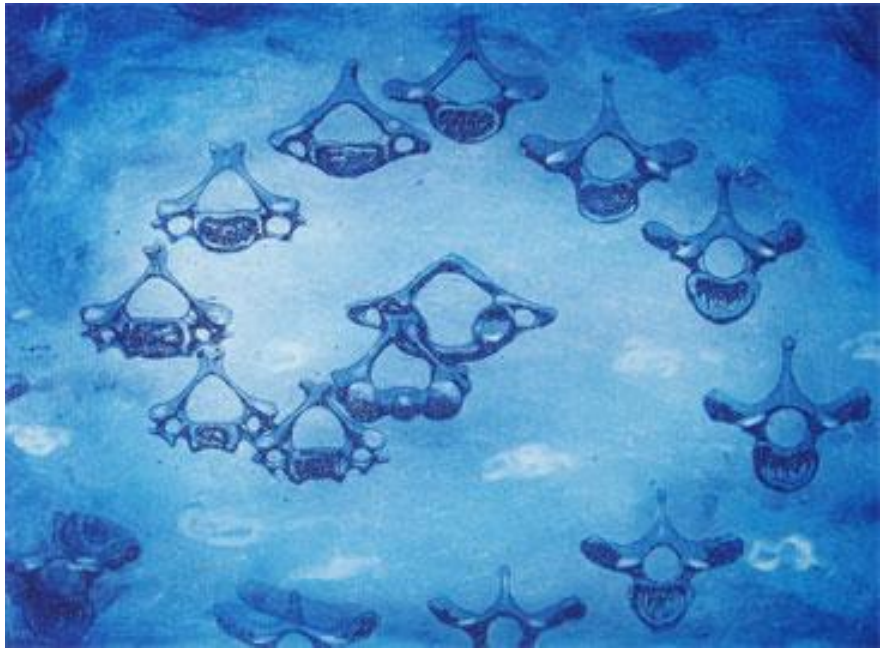
- Studieledelse m prosjektleder
- Sentral koordinator og dataregistrering
- Gode lokale koordinatorer
  - stillingsandel
- Lokal koordinator må ikke være lege
- Datakvalitet – ”monitor”

Multisenterstudier

- Studieledelse/koordinatorer – regelmessig kontakt
- Møtepunkt
  - Kongresser
  - Leger
  - Koordinatorer

Multisenterstudier

- Nettverket må opprettholdes!
  - Planlegge nye studier
- Tverrfaglig samarbeid
- Konsensus
  - Indikasjoner
  - Bruk av implantater
  - Klinisk betydning



The future for neurosurgeons and orthopedic surgeons

Delstudie 1
Helseøkonomi

- Helseøkonomisk evaluering av skiveprotese sammenlignet med aktiv ryggrehabilitering
- Samarbeid med SINTEF
- Utarbeidelse av KPP verdier (kostnad pr pasient)

Delstudie 1
Helseøkonomi

- Målsetting:
  - Kartlegge alle økonomiske utlegg (personlige og offentlige) for hver enkelt pasient
  - Sammenligne kostnadene ved to forskjellige behandlingsopplegg for degenerativ skivelidelse (cost-effectiveness, cost benefit etc.)

Helseøkonomisk evaluering i skiveprotesestudien

- Bygger på: Sykehuskostnader + pasientkostnader + trygdeutgifter

- Sykehuskostnader pr. pasient:
  - Skiveprotese: Nok 79459.-
  - Rehab.: Nok 34641.-

- Totale utgifter pasienter behandlet i studien:
  - Skiveprotese: 5124650
  - Rehab. : 2772700
- Hovedeffektvariabel : ODI
- Sum effekt (total forbedring i ODI poeng):
  - Protese: 1488 ODI poeng
  - Rehab.: 590 ODI poeng

ICR (incremental cost ratio)

- Det vil si: Kostnad pr. ODI poeng:

5124650 – 2772700/ 1488 – 590

= 2619 pr ODI poeng

Tolking: Det koster 2619 kr mer å redusere ODI med ett prosentpoeng ved hjelp av kirurgi vs rehab

History in Norway

- Orthopedic surgery in Norway
  - Defined as a speciality in 1918
  - Norwegian orthopedic society 1947
- Neurosurgery in Norway
  - Defined as a speciality in 1953
  - Norwegian neurosurgical society 1965

Spinal surgery in Norway

- Neurosurgeons: 84
- Orthopedic surgeons: 644
- Neurosurgery/orthopedic rate: 1/8
- Spinal surgery
  - Orthopedic surgeons?
  - Neurosurgeons?

The National Register for Back Surgery 2007

The relationship between surgeons and rates of back surgery

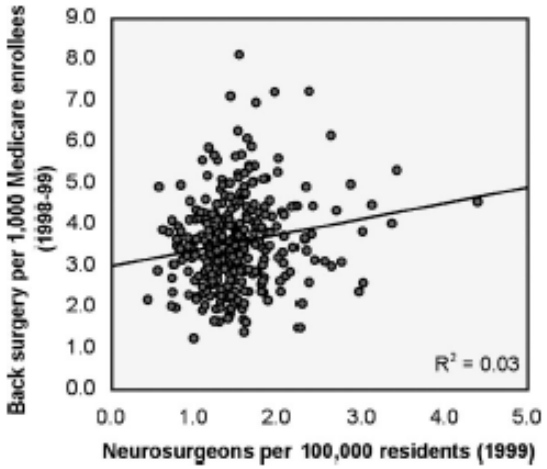


Figure 8. The relationship between neurosurgeons per 100,000 residents (1999) and rates of back surgery (1998–1999).

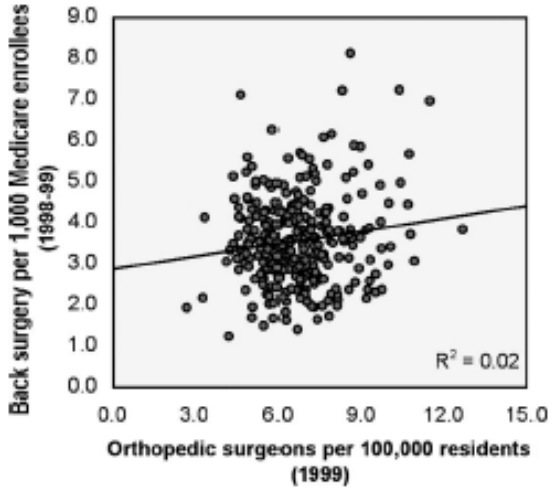


Figure 7. The relationship between orthopedic surgeons per 100,000 residents (1999) and rates o

Weinstein Spine 2006

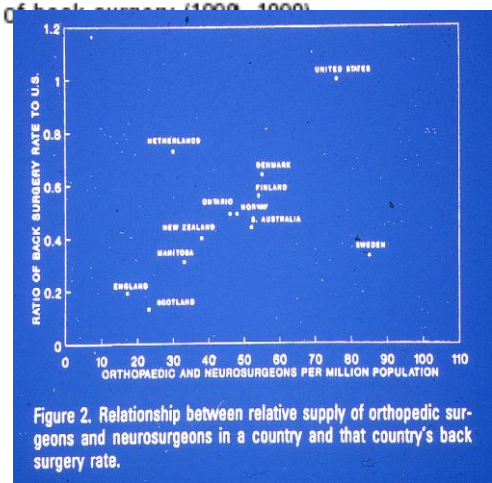


Figure 2. Relationship between relative supply of orthopedic surgeons and neurosurgeons in a country and that country's back surgery rate.

SPINE Volume 30, Number 19, pp 2208–2213

Variation in Surgical Decision Making for Degenerative Spinal Disorders. Part I: Lumbar Spine

Zareth N. Irwin, MD,* Alan Hilibrand, MD,† Michael Gustavel, MD,‡ Robert McLain, MD,§ William Shaffer, MD,|| Mark Myers, MD,¶ John Glaser, MD,# and Robert A. Hart, MD**

- Ortopedic surgeons advice more fusion
- Age of surgeon plays a role
- ”Surgeons preference”

Our own experience
St. Olavs Hospital

- National center for spinal disorders (2003)
- Possibility to establish a true multidisiplinary department
  - Orthopedic surgeons, neurosurgeons, neurologist, neuroradiologist, rehabilitation specialists, physioterapists, PhD students, research assistants, nurse
- Both clinical investigations/invasive treatment and clinical research

Common meetingplaces

- Localized at the same floor
- “core” time one day of the week
- Clinical and scientific meetings
- Evaluation and treatment of common patients
- Multidiciplinary clinical trials

Erfaringer

- Vitenskaplig
- Helsepolitisk
- Kompetanseoppbygging
  - Drive randomiserte studier
  - Helseøkonomi
  - Biomekanikk

Entusiasme - kurven

"Why fuse when you can preserve motion??"

"The body is made for motion"

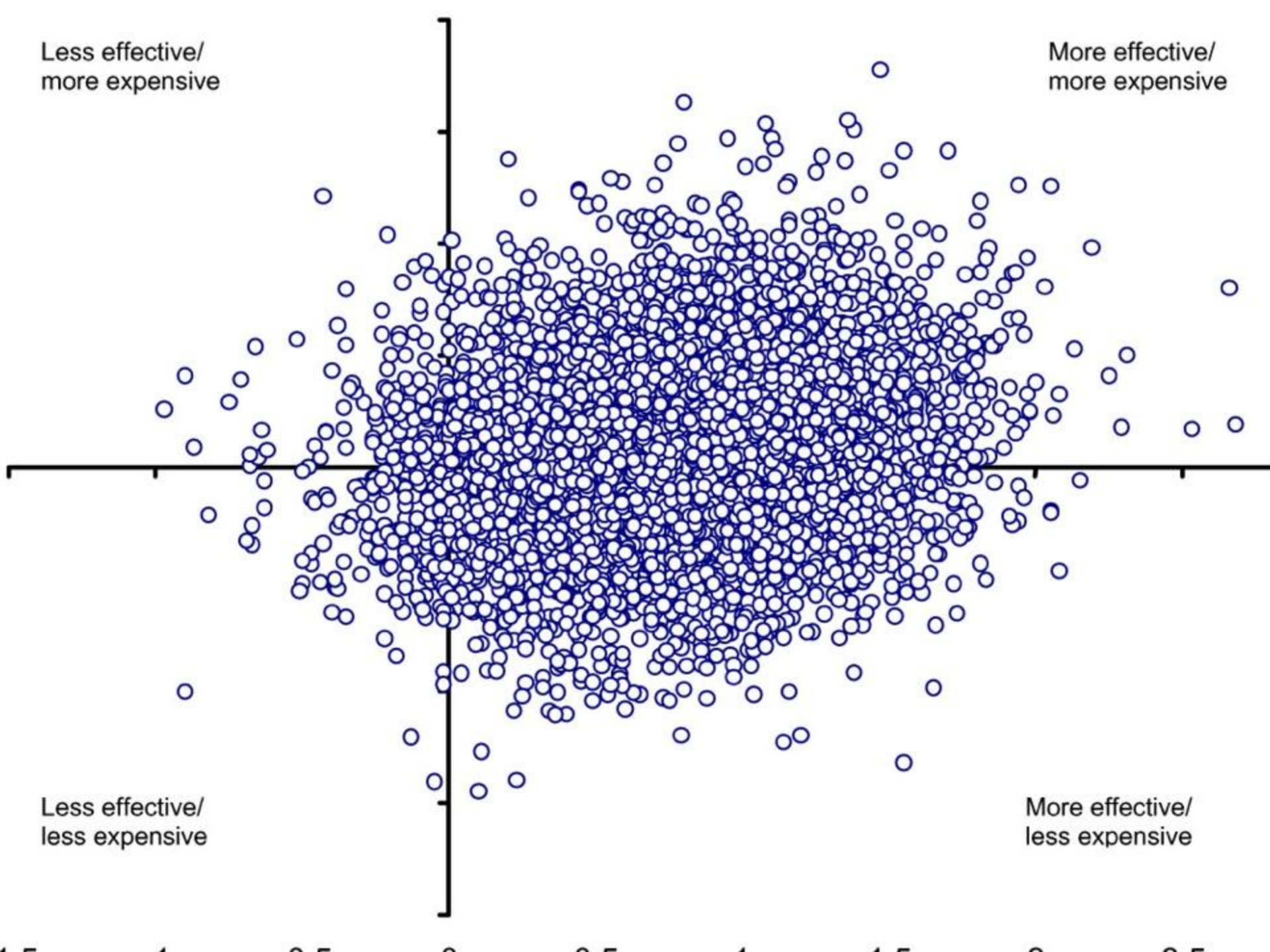
Lumbal skiveprotese vs tverrfaglig ryggrehabilitering

- Standard kirurgisk behandling: fusjon
  - Ingen god kirurgisk behandling
  - Bedring på ca 15% på Oswestry Disability Index (ODI)
- Lumbale skiveproteser??

- 2 RCT`s på skiveprotese versus fusjon
  - Blumenthal et al 2005 (Charite)
  - Zigler et al 2007 (Prodisc)
- 3 RCT's på fusjon versus tv
  - Fairbank et al 2005
  - Brox et al 2003 og 2006

Ingen vesentlige forskjeller mellom fusjon og tverrfaglig rehabilitering

- Norsk standard for systematisk tverrfaglig ryggrehabilitering
  - Videreutvikling av Åge Indahls metoder


Less effective/
more expensive
More effective/
more expensive
Less effective/
less expensive
More effective/
less expensive