Dr. J.W. Scott’s parabola and the medical-industrial complex

Scott’s Parabola

The rise and fall of a new surgical technique

- Promising idea
- Possible value as research tool
- Operating staff ponder uses for large quantities of expensive obsolete equipment
- Encouraging reports
- Widespread enthusiasm
- General introduction
- Strong media pressure
- Doubts creep in
- Damaging survey reported
- Publicised medico-legal cases
- Condemned by several authorities
- Ancient surgeons amaze their juniors with rollicking stories of the old days
- Used only in highly specialized circumstances
- Mostly published methodological care
- Encouraging reports
- Standard treatment
- Strong media pressure for universal acceptance
- Operating theater staff ponder possible uses for large quantities of expensive, obsolete equipment
- Ancient surgeons amaze their juniors with rollicking stories of the old days

Disclosures

- Consultant: Trimed Co
- AO Foundation
- Stock: OHK Co
- Research: AO foundation
- Reviewer: Elsevier; Springer; Walter Klower
- Editor: Walter Klower
- Committee: AAHS; ASSH; AAOS

I certify that, to the best of my knowledge, no aspect of my current personal or profession situation might reasonably be expected to affect significantly my views on the subject on which I am presenting.
Dr. J.W. Scott’s parabola and the medical-industrial complex

Solution in the 1990’s

- Precontoured but flexible design
- Option of buttress pins anchored into plate
- Recessed screw holes
- Self tapping screws

AO/ASIF Hand Study Group
Distal Radius Plate

Jesse B. Jupiter, MD
Ueli Buchler, MD
Jurg Brennauld, MD
Hill Hastings, MD

Scott’s Parabola
The rise and fall of a new surgical technique

Promising idea
Encouraging reports
Possible value as research tool
Scott, J W BMJ 2001:323:1477
Prospective Multicenter Trial of a Plate for Dorsal Fixation of Distal Radius Fractures

David Ring, MD, Jesse B. Jupiter, MD, Boston, MA, Jürg Brennwald, PD, MD, Basel, Switzerland, Ulrich Büchler, MD, PD, Bern, Switzerland, Hill Hastings II, MD, Indianapolis, IN

A new plate designed specifically to address complex wrist pathology was used for the internal fixation of 22 complex fractures of the distal radius in 22 patients in a prospective multicenter trial. The majority of fractures were group C2- and C3-type fractures according to the Comprehensive Classification of Fractures. No plate failures, loss of reduction, nonunions, or infections occurred. Within the average follow-up time of 14 months, the functional results (including an average motion of 76% and an average grip strength of 56% of the contralateral side) were comparable to those reported for similar fractures in previous investigations. Five patients had irritation of the tendons in the second dorsal compartment. This trial serves both as a verification of the safety and efficacy of this distal radius plate as well as a demonstration of its utility in the treatment of complex fractures of the distal radius. (Hand Surg 1997;22A:777-784.)

Scott’s Parabola

The rise and fall of a new surgical technique

Standard treatment

Promising idea

Possible value as research tool

Strong media pressure

General introduction

Encouraging reports

Widespread enthusiasm

Damaging survey reported

Doubts creep in

Scott, J W BMJ 2001;323:1477
π Plate--problems

- Design ??
- Metallurgy ??

Scott’s Parabola

The rise and fall of a new surgical technique

- Standard treatment
- Doubts creep in
- Strong media pressure
- General introduction
- Damaging survey reported
- Encouraging reports
- Publicised medico-legal cases
- Operating staff ponder uses for large quantities of expensive obsolete equipment
- Ancient surgeons amaze their juniors
- Possible value as research tool
- with rollicking stories of the old days

Scott, J W BMJ 2001;323:1477

“Emerging” Orthopaedic Technologies

Chymopapain disc injections
- Pioneered by Dr. Lyman Smith
- 7000 US surgeons “trained”
- Complications – paraplegia, stroke

Chymopapain 1984

Chymopapain 1986
"original industry-sponsored trials ...were remarkable for the complete absence of reported rhBMP-2–related clinical adverse events..."

"...most cursory review shows that this was all about devices and drugs used in an off-label manner...

"...some clinical researchers in the current "market environment" cannot be trusted to resist enormous financial forces that encourage biased reporting..."

"...our patients remain our number one priority. We need to fulfill their trust."  

OBJECTIVES

- Examine existing problems with our scientific studies
- Bring into focus the “medical-industrial complex” on health care
- Evaluate perspectives on our relationships with industry and research

Musculoskeletal Research System

- Rewards positive results
- Little motivation to perform negative studies or those that duplicate prior published results
- “Positive” trials and “negative” trials take the same amount of time to conduct but “negative” trials take 2-4 years longer to be published
Musculoskeletal Research
“Evidence-based Triad” vs “Orthopaedic Triad”
Dr Freddie Fu

• Combining best available evidence with
• Clinical expertise of the physician
• And the expectation and value of the patient

• Famous surgeon
• Famous athlete
• Untested treatment

Famous People’s Hip
Jack
Jimmy
Mary Lou

Douglas Jackson MD
Orthopaedics today, June 2012

• “Reproducibility of published work is only occasionally challenged by knowledgable scientists and clinicians who work in the same field or by industry when it tries to duplicate results before proceding with product development”

“In contrast, successful venture capitalists will be more inclined to reproduce results by independent observers before committing to early funding”

Dr John P. Ioannidis
Stanford’s Prevention Reseatch Center

‘In many different ways, much of what biomedical researchers conclude is misleading, exaggerated, and at times wrong’
Dr. John P. Ioannidis

• 2005 landmark paper in PLoS Medicine, demonstrated convincingly in # studies in different fields of medical research
a) 80% of non-randomized turn out to be in error
b) 25% randomized controlled trials also flawed
c) 10% of “platinum” large clinical trials flawed

Dr. John P. Ioannidis
Stanford

• In randomized controlled trials, he found it was easy to manipulate results at every step
• room to distort results
• make a stronger claim
• or select what is going to be concluded “Intellectual conflict of interest”

Dr. John P. Ioannidis
Stanford

randomized controlled trials-- range of errors

• What questions researchers asked
• How they set up the study
• Which patients were included
• Which measurements used
• How data analyzed
• How results presented
• How studies came to be published

Dr. John P. Ioannidis
Stanford

• Studied 49 of most highly regarded research findings in medicine over prior 13 yrs
• 45 claimed to have uncovered effective interventions
• 34 had been retested with 14 or 41% shown to be wrong or substantially exaggerated results
Notes that much of the wrongness problem could be solved if the world simply stopped expecting scientists to be right. But as long as careers remain contingent on producing a stream of research that is dressed up to seem more right than it is, scientists will keep delivering exactly that.

“Science is a noble endeavor, but it is also a low-yield endeavor. I’m not sure that more than a very small % of medical research is ever likely to lead to major improvements in clinical outcomes and quality of life. We should be very comfortable with that fact.”

OBJECTIVES

- Examine existing problems with our scientific studies
- Bring into focus the “medical-industrial complex” on health care
- Evaluate perspectives on our relationships with industry and research

The Medical Industrial Complex: Understanding the Business of Medicine
Michael R. Mills, MD, MPH
February 2012

Graph 1: Escalation of healthcare costs as a percentage of GDP

The American Health Enterprise: Power, Profits, and Politics
Barbara Ehrenreich

- Among the first to introduce the term “medical-industrial complex”
President Dwight D. Eisenhower
Farewell Address Jan 17, 1961

- Warned the nation of the risks of an emerging “military-industrial complex”
- Growing dependence of universities and research labs for federal funds
- Potentials to compromise researchers in their search for truth as well as reduce the “scholar” to an “obedient servant”

Dr Michael Mills
Medical-Industrial Complex

- 3 Trillion dollar industry
- One of fastest growing business in USA
- Interaction of MDs, other providers, hospitals, nursing homes, insurance co., pharma et al.

The Social Transformation of American Medicine
Paul Starr 1982

- Landmark study of the social and economic development of medicine in America
- Final chapter “The Coming of the Corporation” describes the new corporate transformation of the United States health care system and its growing threat to the sovereignty of physicians
Dr. Arnold Relman  
NEJM 1980

- “Corporatization of medicine is a challenge to physicians’ authority, and even legitimacy for doctors who become healthcare industry owners or with financial stake in industry”

Stanford U  
San Jose Mercury News 2006

- For # years most researchers in life sciences had little to do with corporations
- In 1970s the venture capital community noticed advances in molecular biology
- Dr Stanley Cohen working with Dr Herbert Boyer at UCSF invented a technique that allowed mass production of human proteins giving birth to the new biotech industry.

Dr. Arnold Relman

- “Doctors are not saints, but not sinners either. They are sensible, pragmatic, decent”
- “Argued that if physicians are to represent their patients interests in the new medical marketplace, they should have no economic conflict of interest”

Dr Paul Berg  
Nobel Laureate

- Over his objections Stanford in 1974 filed for patents on the Cohen-Boyer invention
- Ultimately brought Stanford 225 million in fees and royalties
- Ushered in a new era of financial opportunities for the school and its scientists
Dr. Paul Berg  
Nobel Laureate

- “like anything, there is an upside and downside. What is happening is that the lure of money begins to erode how careful you are guarding against the downside....I myself just think that things have shifted too far towards commercialization”

Dr. Barbara Koenig  
bioethics research Mayo Clinic

- “ there is a focus on procedural solutions and the magical belief that disclosure is the answer as opposed to dealing with the fact that many of these things should not be allowed”

Dr. Sidney Levitsky  

- “ Corporatization and the need for adjustment for financial survival has forced many academic centers to move the original mission from teaching, research, and clinical care to become outstanding profitable care providers using clinical research as a profit-center”

No Margin  No Mission
“If you listen to what a lot of our political leaders say, they believe that industry is a bunch of people that get together every morning and say “what new innovation can we make that is more expensive, less effective, and maybe kill babies just gratuitously”

President Dwight D. Eisenhower
Farewell Address Jan 17, 1961

• “We must guard against the acquisition of unwarranted influence, whether sought or unsought, by the military-industrial complex”

Ioannidis. “But as long as careers remain contingent on producing a stream of research that is dressed up to seem more right than it is, scientists will keep delivering exactly that”
Senator Grassley

Senator Kohl
Chairman

Surgeons for Sale: Conflicts and Consultant Payments in the Medical Device Industry
3/27/2008

"These types of unethical payments have been pervasive and industry-wide for far too long. "If these physicians are essentially putting their medical judgment up for sale, where does the patient’s well-being fit into the equation?"

Senator Grassley

Historic Regulation of Drugs and Devices

1207 – 1272
Henry III of England
Decreed the Assize of Bread and Ale

1813 Vaccine Control Act
guard against adulterated smallpox vaccine

Edward Jenner

1902 Biologic Control Act
passed in response to death of 13 children in St. Louis and 9 children in Camden due to improper vaccine preparation

Horse named Jim produced diphtheria anti-toxin serum contaminated with tetanus
1906 Pure Food and Drug Act
Upton Sinclair – exposed unbridled capitalism and corruption in meatpacking industry. Considered the founding date of FDA

1938 – Federal Food Drug and Cosmetic Act
The introduction of this act was influenced by the death of more than 100 patients due to a sulfanilamide medication was dissolved in diethylene glycol

1962 Kefauver - Harris Amendment
Legislation in response to Thalidomide Disaster. For the first time a drug must be safe and effective.

Dalkon Shield
• Intrauterine birth control device - Inventor Hugh J Davis MD – Johns Hopkins professor of gynecology
• Sold rights to A H Robbins in 1971 for $750,000. and 10% of sales.
• Heavily market on basis of single study by Davis
• Study claimed 1.1% failure rate – actual rate 5.5 % - facts known and concealed by company
• Used by 2.8 million woman, 300,000 lawsuits
• Flawed design responsible for birth defects, sepsis and death

Root Causes Dalkon Shield Disaster
• Dishonesty – Dr. Davis claimed a 1.1% failure rate in his study - actual rate 5.5%
• Dr. Davis instructed study patients to use spermicide – never disclosed.
• Dr.Davis later added copper to IUD to improve contraception rate - not disclosed
• Design Flaw – Only IUD on Market with a braided string – caused wicking of bacteria.
Dalkon Shield

Billions in legal fees and settlement
2 billion dollar trust fund for patients over 15 years
bankruptcy for AH Robbins

Dalkon Shield Disaster

- Corporate Greed – AH Robbins knew almost from the beginning of problems but marketed heavily. Withheld and destroyed information.

Prompted Congress to enact Medical Device Amendment Act of 1976
For the first time the FDA regulated medical devices

The Medical Device Amendment Act of 1976

Congress gave FDA authority to classify and regulate medical devices

Medical Device – A contrivance intended to affect the structure or any function of the body of man, and which does not achieve any of its primary intended purposes through chemical action within or on the body

- insulin
- insulin pump
- total shoulder
- drug eluting stent

- drug, not a device
- medical devices
- combined device

FDA classification of Medical Devices

- Class I – non critical devices
  no premarket notification

- Class II – premarket notification needed
  may need premarket data
  may need post market surveillance
  usually approved with 510K process

- Class III – critical devices, used to support life or bodily function. Needs premarket approval (PMA) (with exception).
FDA Class I Medical Device

47% of medical devices are class I
95% are exempt from regulation

FDA classification of Medical Devices

• Class I – non-critical devices
  no premarket notification

• Class II – premarket notification needed
  may need premarket data
  may need post-market surveillance
  usually approved with 510K process

• Class III – critical devices, used to support life or bodily function. Needs premarket approval (PMA) (with exception).

FDA Class II Medical Device

Electric wheelchair  total hip replacement  infusion pump  total knee replacement

43% of all devices
Requires premarket notification

Highly cross-linked polyethylene

FDA classification of Medical Devices

• Class I – non-critical devices
  no premarket notification

• Class II – premarket notification needed
  may need premarket data
  may need post-market surveillance
  usually approved with 510K process

• Class III – critical devices, used to support life or bodily function. Needs premarket approval (PMA) (with exception).
FDA Class III Medical Device

- 10% of medical devices
- Requires premarket approval (PMA)
- 3 to 5 year costly process

heart valve  pacemaker

- surface replacement
- mobile bearing knee
- ceramic total hip

“The committee concludes that the 510(k) process lacks the legal basis to be a reliable premarket screen of the safety and effectiveness of moderate-risk devices and furthermore, that it cannot be transformed into one.”

Institute of Medicine Report
Medical Devices and the Public’s Health
July 2011

OBJECTIVES

- Examine existing problems with our scientific studies
- Bring into focus the “medical-industrial complex” on health care
- Evaluate perspectives on our relationships with industry and research

TOO FAR???
**Medicine’s industrial revolution**

J.D Kleinke          Wall St J 1995

• “Many physicians are understandably threatened by this watershed in the history of medicine, this challenge to 2500 years of clinical hegemony. From unquestioned GOD to accountable production worker is a long way to fall in a few short years”

---

**Thomas J. Stossel M.D**

Professor of Medicine

Harvard Medical School

• ”a small minority of voices is impeding medical and scientific progress with their concerns regarding potential ‘conflicts of interest’ by decrying the beneficial relationships between industry and medicine”

---

**Thomas J. Stossel M.D.**

• “It has gone from bad to worse. Immense regulatory issues and massive confessions where we disclose our relationships to industry and these are used to initiate a whole variety of inhibitors in freedom of speech, freedom of association, and reward for excellence”

---

**Thomas J. Stossel M.D.**

• “Believe that those in industry allegedly live in a separate moral universe than medicine. The idea that those who work for industry are obligated to lie, cheat, and steal for profit and for investors”
• “Medical care is incomparably better today than when I received my MD degree in 1967—due primarily to the availability of products developed by industry in unencumbered collaboration with physicians and industry’s commitment to teach physicians how to use them”

• “Evidence that collaborations ‘compromise integrity and patient care is ‘practically nonexistent’

• 2009 Institute of Medicine report on conflict of interest was unable to find evidence that relationships with industry adversely affect what really counts—patient outcomes

“Who doesn’t really care? Consumers don’t as few patients have the time, interest, or competence to interpret disclosures. Most surveys show that patients have few concerns regarding the physician-industry relationship”

Patients’ Views on Surgeons’ Financial Conflicts of Interest
Camp MW et al Orthopaedic Forum JBJS 2013

Surveyed 251 post op patients in USA and Canada
Few patients worried about financial relationships with industry (6%)
Most thought appropriate for surgeons to receive payments for activities that could help patients (US 69%; Canada 66%)
Majority felt that their surgeon would hold patients’ interests paramount (US 79%; Canada 74%)
Most wanted professional organizations to ensure oversight (US 83%; Canada 83%)
What can we do about this?

Dr. J.W. Scott’s parabola and the medical-industrial complex

"Yet harm has been done. And that fact creates a basic moral obligation. As John F. Kennedy stated, ‘This moral issue is as old as the scriptures and is as clear as the American Constitution.’"
“use of media by some unscrupulous, megalomaniac orthopedists... is an example of the growing collapse of professionalism...”

"medicine is no longer a profession but a business, were profit is the name of the game...”

“education of the orthopedist is primarily structured to satisfy the marketing needs of industry...”

“(orthopedists) lowered themselves to playing the role of agents for industry... (to help) the sales of products from which they receive royalties or kickbacks.”

Andrew Manson, M.D. – A once idealist physician, now corrupted by a "Harley Street" avarice.

Mr. Joseph LeRoy – a pharmaceutical industrialist, making a proposal to Dr. Manson

Mr. LeRoy talking to Dr. Andrew Manson...

“we can enlist the help and sympathy of the whole medical profession, make every doctor, so to speak, a potential salesman”

“now this means scientific advertising, Doc, scientific approach and that’s were I believe a young scientific doctor on the inside could help us along the road.”

Moral Hazzard

Economist Paul Krugman described moral hazard as: "...any situation in which one person makes the decision about how much risk to take, while someone else bears the cost if things go badly

Be not the first by whom the new are tried, nor yet the last to lay the old aside.

Alexander Pope, An Essay on Criticism, 1711
The Care of The Patient

“One of the essential qualities of the clinician is interest in humanity, for the secret of the care of the patient is in the caring for the patient.”

JAMA
March 19, 1927
Francis Weld Peabody
