WHEN DOES PRODUCT LIABILITY RISK CHILL INNOVATION? EVIDENCE FROM MEDICAL IMPLANTS

Alberto Galasso
University of Toronto and NBER

Hong Luo
Harvard Business School

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Motivation

Product liability laws protect customers from defective and dangerous products

E.g., in 2012 GSK paid about $3 billion in penalties and settlements for a diabetes drug linked to high risk of heart attack and stroke.

How does liability risk affect the rate and direction of innovation?

February 2017 European Parliament resolution with recommendations for EU-wide legislation to regulate "*sophisticated robots, bots, androids and other manifestations of artificial intelligence*" and to establish legislative instruments related to the *liability for their actions*

Dominant view: liabilities are bad for innovation!

"In the United States product liability is so extreme and uncertain as to retard innovation. The legal and regulatory climate places firms in constant jeopardy of costly and, as importantly, lengthy product liability suits."

Michael Porter (1990)

Dominant view: liabilities are bad for innovation

This negative view:

- is shared by legal scholars: Huber (1989); Parchomovsky and Stein (2008)
- has shaped high-profile cases (2007 Riegel v. Medtronic Supreme Court)
- is a key argument for tort reforms

Systematic empirical evidence is scarce. Two existing large-sample studies **do not support** this dominant view:

- Viscusi and Moore (1993)
- Galasso and Luo (2017)

Under what conditions does liability risk retard innovation?

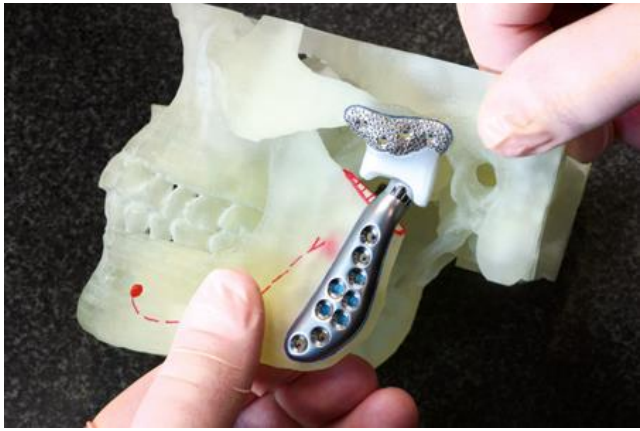
This paper identifies and examines empirically an environment in which high liability chills innovation

Setting: Medical implants and biomaterials

Medical implants: devices that are placed inside or on the surface of the body

Implants are produced using **biomaterials** direct or modified applications of common materials (metals, polymers, ceramics, etc..)

Biomaterials often ***produced by large companies*** that supply a wide range of sectors in the economy



Temporomandibular Jaw Implant (TMJ)

Silicone Breast Implant

Dupont's Teflon Polytetrafluoroethylene (PTFE)

Implant litigation in late 80s and early 90s

1983 Vitek's TMJ (jaw) implant was approved by FDA

~1987 serious problems started to surface

1990 Vitek filed for bankruptcy

DuPont - large 'deep-pocket' supplier - faced costly litigation:

651 lawsuits involving 1,605 implant recipients

$40 mill in litigation costs, revenue was < $50,000 (~5c per device)

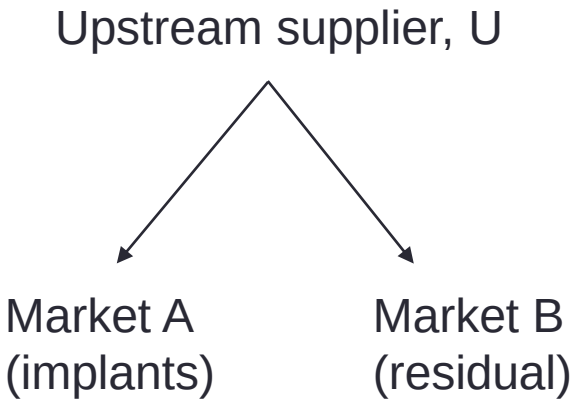
Vitek's bankruptcy triggered an industry shock

Change in regime: for 30 years **standard supply policy** was **not to withhold materials** from the medical sector, even if revenue negligible, the TMJ litigations made companies rethink these industry practices

In 1992, DuPont withdrew from supplying *all permanent implant producers* (not only TMJs and breast implants!) and not only Teflon, *many other polymer/silicone suppliers followed* suit ~60 percent of material suppliers were unwilling to supply medical implants producers. No change for non-implant devices (Aronoff, 1995)

Dramatic increase in the perceived risk and uncertainty of liability litigation!

Theoretical framework



Key assumptions:

- B is large compared to A
- homogeneous product, U cannot price discriminate between A and B
- innovation investment in U and A
- each unit sold in market A generates a liability cost to U with some probability

What happens when liability risk increases?

If increase is large enough, U may decide to foreclose A and focus on B. Innovation drops in A but not in U

Insights:

- foreclosure can be driven by liability risk (overlooked by IO literature)
- liability risk can percolate through vertical chain and affect innovation of companies not directly targeted by litigation

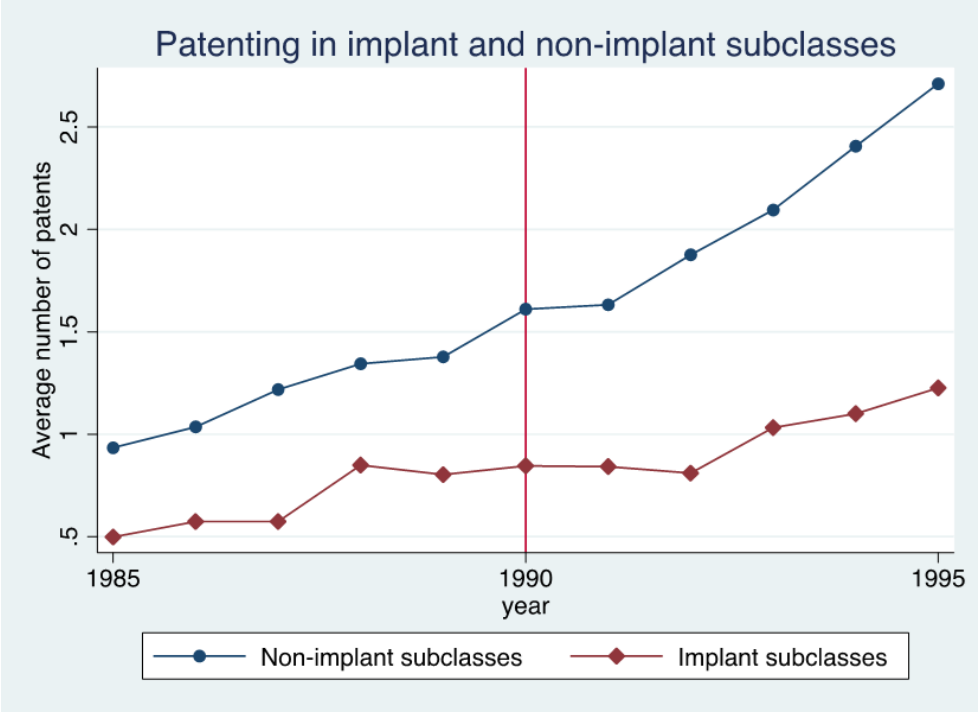
Data

Medical-device patent data from the USPTO

- 2,699 unique sub-classes (Moser and Voena, 2012)

Categorize sub-classes into ‘treatment’ and ‘control’ groups

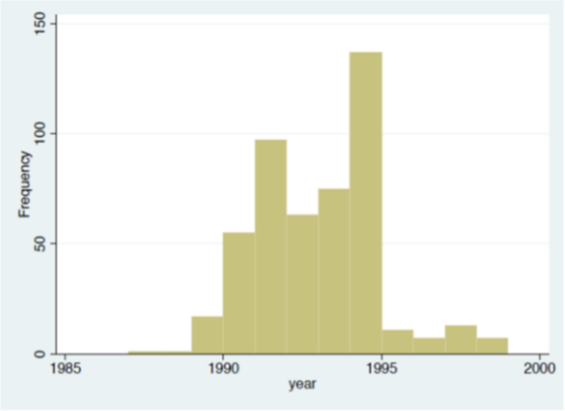
- use patent texts to identify ‘implant patents’
- define treatment subclasses if fraction of implant patents > 80%
- test algorithm with team of science students manually categorizing ~500 patents



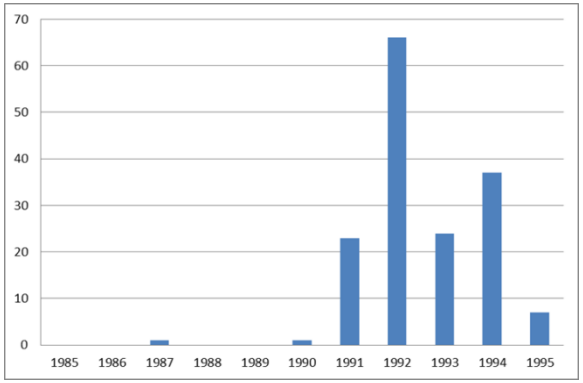
Endogeneity concerns

- We exclude TMJ subclasses

- We discuss evidence supporting that the increase in liability risk was ***unexpected:***
  - Industry publications make clear it was unexpected
  - Interview with Ross Schmucki, senior counsel of DuPont at that time "*This sort of mass tort product liability litigation against a raw material supplier was unprecedented and unexpected by the medical device industry and by material suppliers*"



Du Pont's litigation



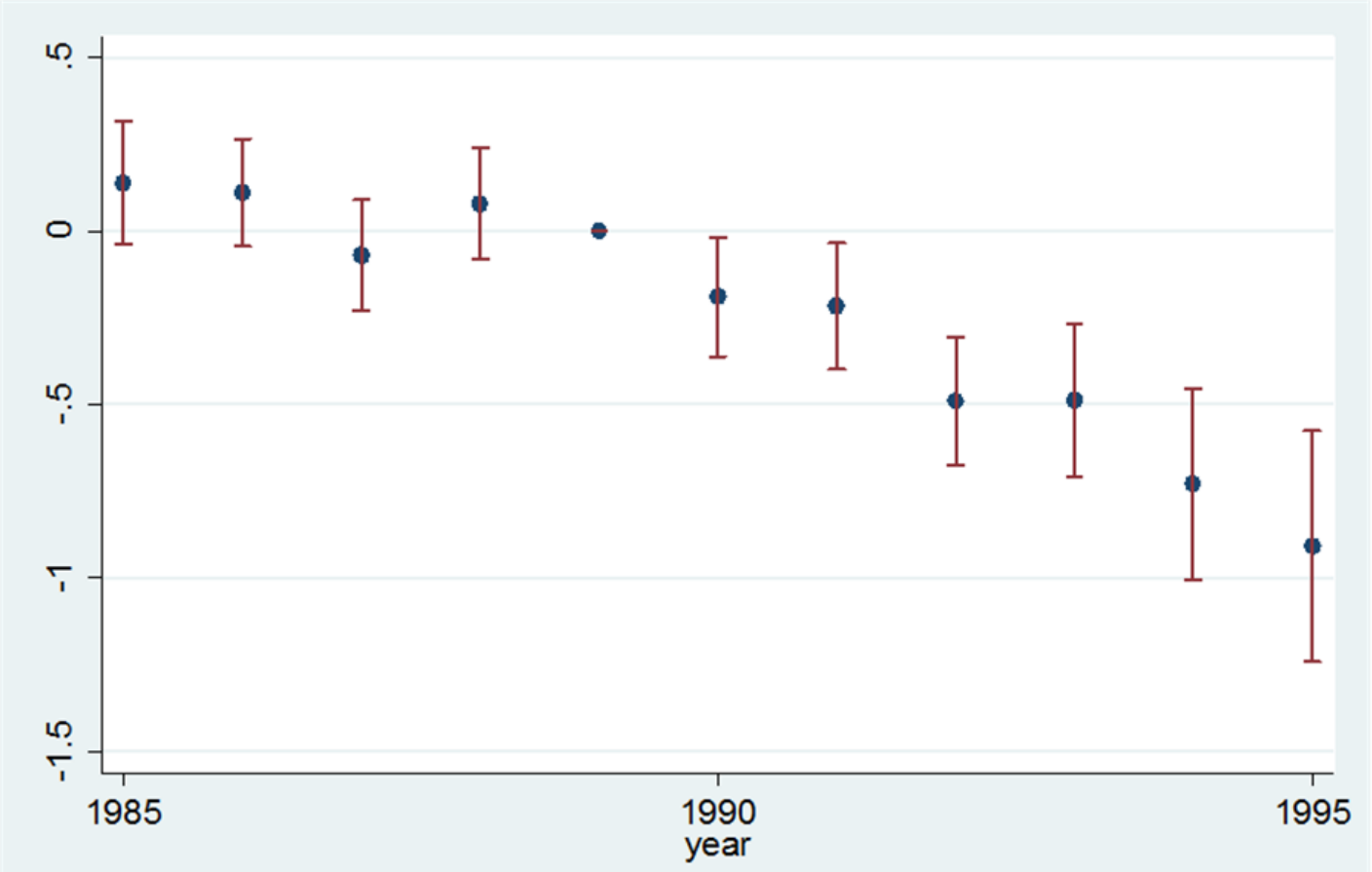
Media coverage

Baseline results

	(1)	(2)	(3)
Dep. variable	Patents	Patents	Patents
Implant x After 1990	**-0.557*** **	**-0.350*** **	**-0.558*** **
	(0.084)	**(0.097)**	**(0.105)**
Year effects	YES	YES	YES
Subclass effects	YES	YES	YES
Cut-off for implant subclass	0.8	0.5	0.9
Observations	29656	29656	29656

Decline is ~35 percent

Timing of the effect



Substitution toward non-implant patents

Drop in implant patenting compensated by re-direction of R&D toward non-implant medical devices?

	(1)	(2)	(3)
Dep. variable	Patents	Patents	Patents
Implant x After 1990	-0.464***	-0.827***	-0.644***
	(0.052)	(0.105)	(0.140)
Year effects	YES	YES	YES
Subclass effects	YES	YES	YES
Observations	29656	22033	6138
Sample	drop assignees that patent in both implant and non-implant subclasses	implant and drug subclasses	implant and matched drug subclasses

Substitution account for at most ~17 percent of the decline

Heterogeneous effects

We examine whether decline is present across firms of different sizes (patent portfolios) and patents of different quality levels (citation distribution)

Main findings:

1. Decline in patenting is ***not localized***, it is present across firm size distribution and technology of various importance

2. slightly ***smaller for largest firms*** (6 largest assignees) consistent with industry accounts

3. slightly ***smaller for patents of intermediate value*** (3rd and 4th quintiles). Consistent with Galasso and Luo (2017) finding on *risk-mitigating technologies* and management literature on slack resources (Cyert and March,1963)

Foreign vs US firms

Industry accounts emphasize that impact of shock was predominantly on US firms because US and foreign implant manufacturers differ in the ease of access to foreign polymer suppliers (Aronoff, 1995)

At the same time foreign and US firms:

- likely to experience common technology shocks
- are subject to similar downstream product liability risk

Triple differences

	Patents
Implant x After 1990	-0.106***
	(0.031)
Implant x After 1990 X US firms	**-0.344*** **
	(0.060)
Patents by foreign firms	
US firms	0.454***
	(0.024)
After 1990 X US firms	0.567***
	(0.038)
Implant X US firms	-0.331***
	(0.047)
Year effects	YES
Subclass effects	YES
Observations	59312

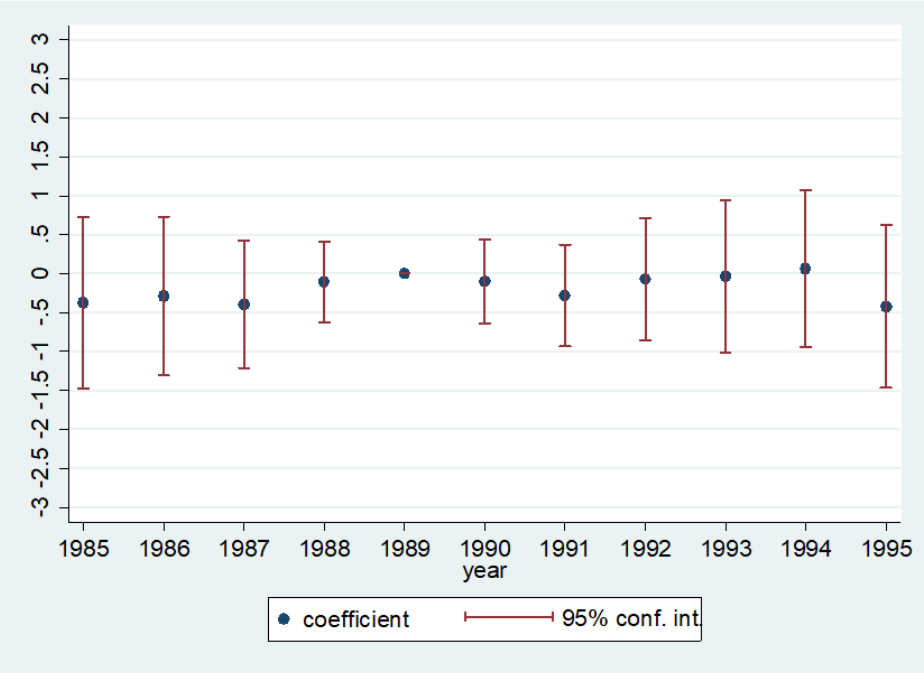
Higher liability risk reduced implant patenting by US inventors relative to implant patenting by foreign inventors

Impact on FDA applications

	(1)	(2)
Dep. variable	applications	applications
Implant code x After 1990	-0.142***	-0.144***
	(0.048)	(0.048)
MDR reports		0.012***
		(0.003)
Year effects	YES	YES
Code effects	YES	YES
Matched Control	YES	YES
Drop outliers	YES	YES
Observations	2464	2464

Combine these effects with estimates in recent working paper by Grennan and Swanson (2017) to estimate drop in surplus per year ~$12B (revenue loss is about 5%)

Upstream analysis

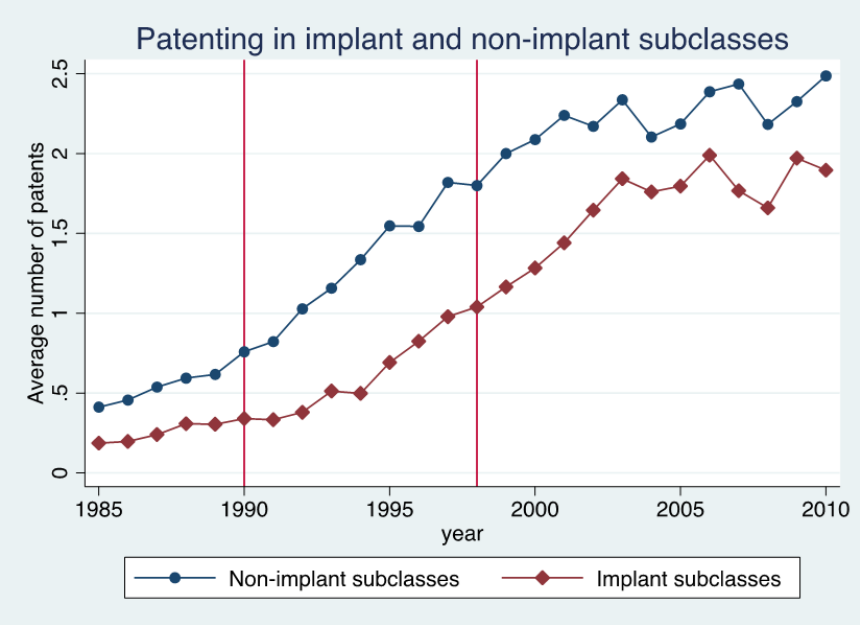


List of key polymers (biomaterials) from congressional hearings

Use textual analysis to identify affected polymers patents and classify “resins and organic compounds” subclasses into treated and control subclasses

No effect even in subsample of DuPont’s patents

1998 Biomaterials Access Assurance Act



DID and triple-differences results are consistent with raw data

Not causal identification: industries could self adjust and state cases won by DuPont might also serve as precedents

Conclusions

Our analysis of medical implant industry provides first empirical evidence of negative effect of liability risk on innovation

Liability risk can percolate through the vertical chain and lead to foreclosure. Channel particularly important for GPTs such as AI (Agrawal, Gans and Goldfarb, 2018)

Suggestive evidence that federal liability-exemption law for suppliers helps restore the pace of downstream innovation

Combined with Galasso and Luo (2017): complex link between liability and innovation

Work in progress (Galasso Luo, 2019)

U.S.

Radiation Overdoses Point Up Dangers of CT Scans

By WALT BOGDANICH OCT. 15, 2009

At a time when Americans receive far more diagnostic radiation than ever before, two cases under scrutiny in California — one involving a large, well-known Los Angeles hospital, the other a tiny hospital in the northern part of the state — underscore the risks that powerful CT scans pose when used incorrectly.

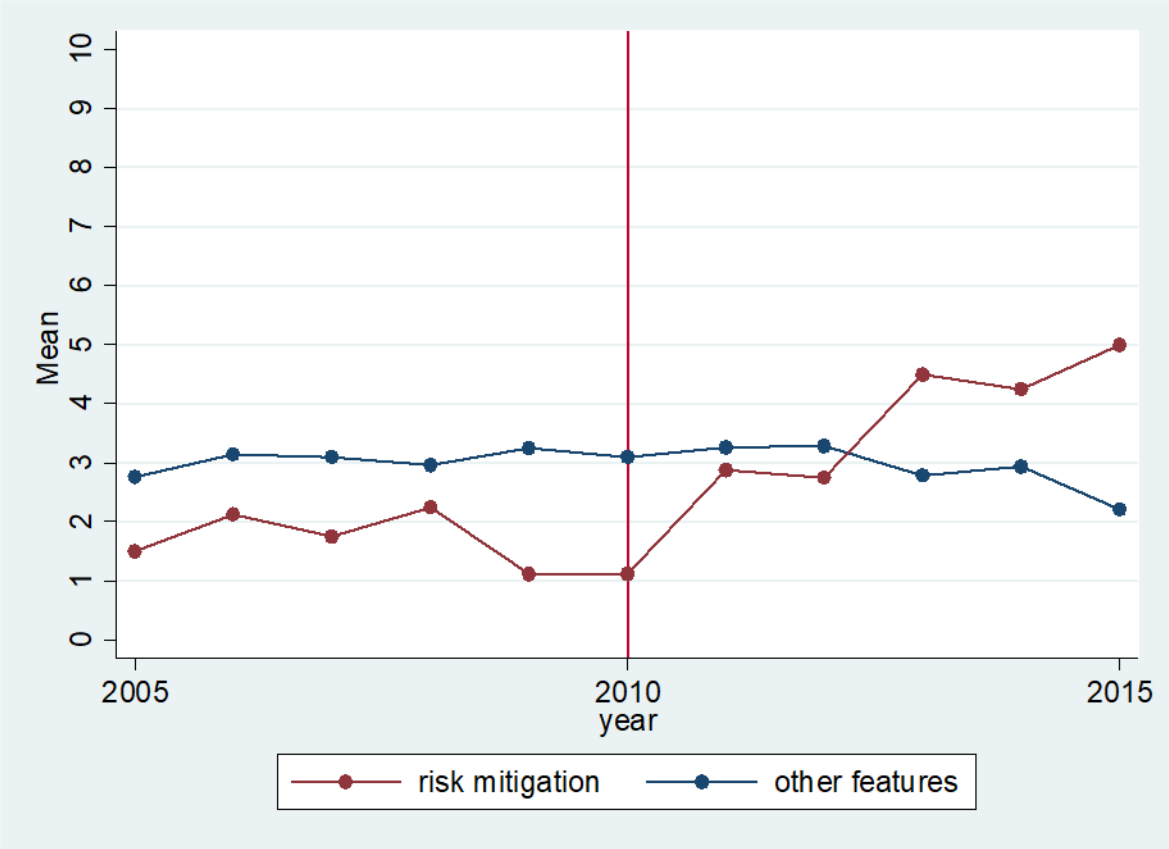
A week ago, Cedars-Sinai Medical Center in Los Angeles disclosed that it had mistakenly administered up to eight times the normal radiation dose to 206 possible stroke victims over an 18-month period during a procedure intended to get clearer images of the brain. State and federal health officials are investigating the cause.

Hundreds of miles north at Mad River Community Hospital in Arcata, the other case — involving a 2 ½-year-old boy complaining of neck pain after falling off his bed — has led to the revocation of an X-ray technician's state license for subjecting the child to more than an hour of CT scans. The procedure normally takes two or three minutes.

The hospital's radiology manager at the time, Bruce Fleck, called the

In October 2009, a medical center in Los Angeles disclosed that it had administered up to eight times the normal radiation to over 200 patients undergoing CT scans because of erroneous scanner settings

Positive effect on innovation!



Thank you!