

Outpatient Artificial Disc Replacement

Scott L. Blumenthal, M.D.

Co-Founder, Center for Disc Replacement at TBI
Clinical Assistant Professor of Orthopedic Surgery
University of Texas Southwestern Medical Center, Dallas, TX
Deputy Editor, *European Spine Journal*

Center for Disc Replacement at Texas Back Institute

Our Clinic



Our Staff



- **Medical Directors**
- **Physician Assistant**
- **Director of Operations**
- **Director of Sales**
- **Care Coordinators**
- **Surgery Schedulers**
- **Medical Assistants**



Services Offered

- **Medical records review for out of state patients**
- **Continuity of staff**
- **Direct phone numbers to clinic personnel**
- **Coordination of initial visit and surgery to minimize travel time**

Team Approach

Medical Directors

- Energetic and motivated to increase volume and productivity
- Understand the business of hospital and healthcare system

Administration

- Development of staff
- Customer Service driven

Medical Tourism

- **>20% of CDR surgeries from outside of “4 County” region**
- **Significant number from outside of Texas**
- **OUS patients:**
 - **Canada**
 - **Mexico**
 - **South America**
 - **Europe (Spain, Germany)**
 - **Israel**

First Arthroplasty in United States

9-yr Follow-up of First Charite



9-yr Follow-up of First Charite

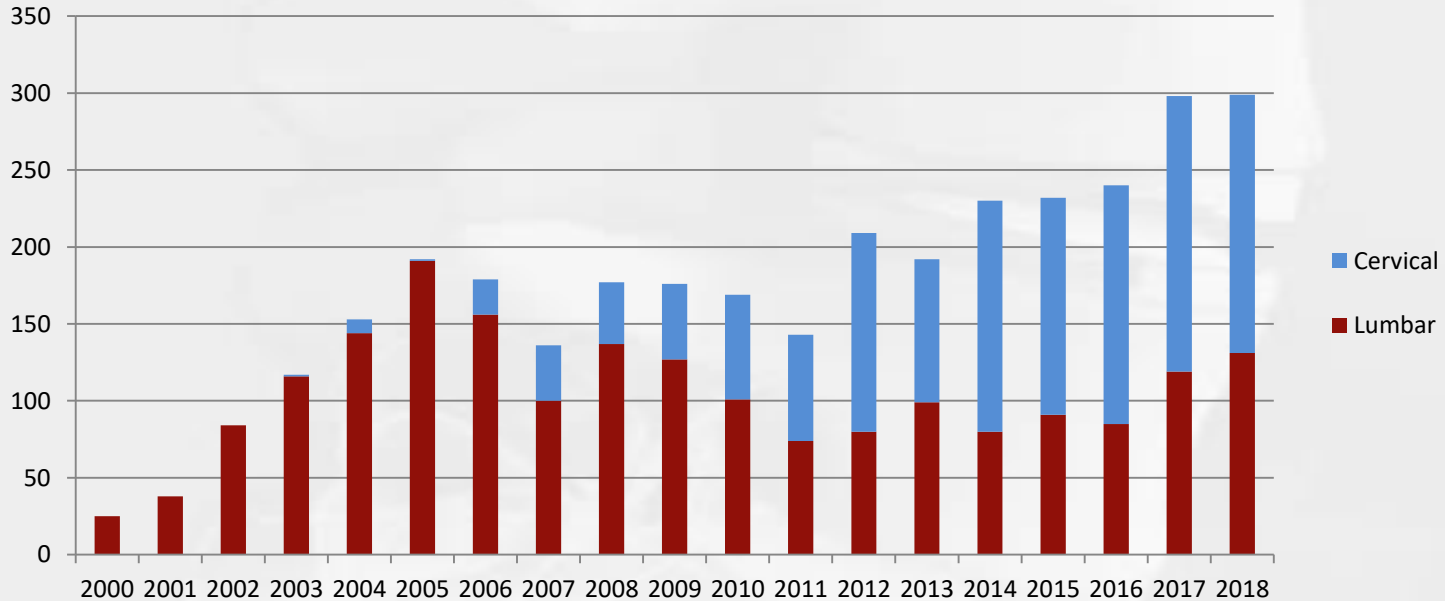


19 years of Studies and Surgeries

- Registry caliber data

TBI TDR Experience

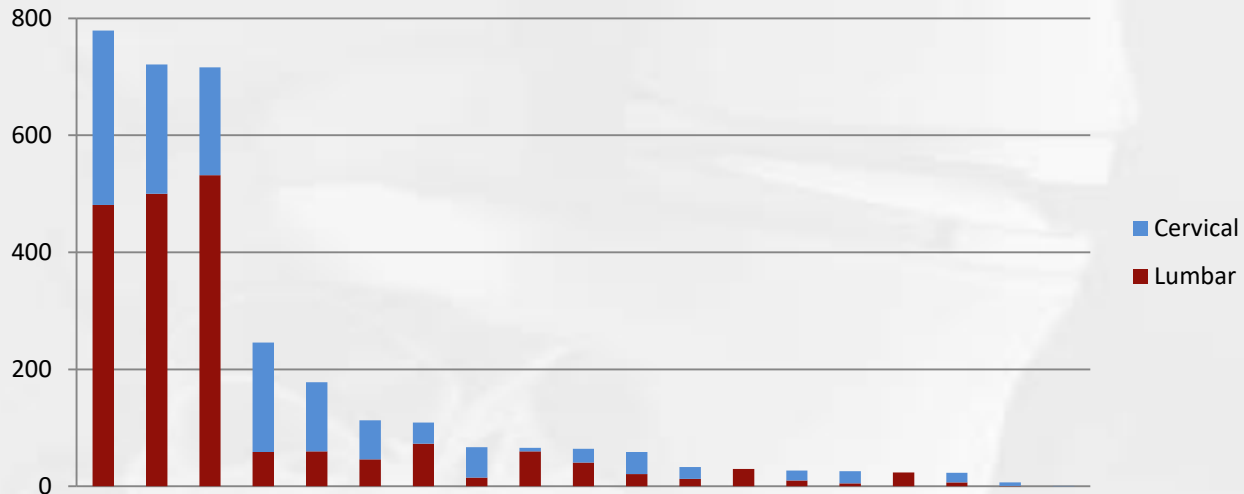
Number of TDR Cases per Year



	Total
Lumbar	1,978
Cervical	1,311
Total	3,289

TBI TDR Experience

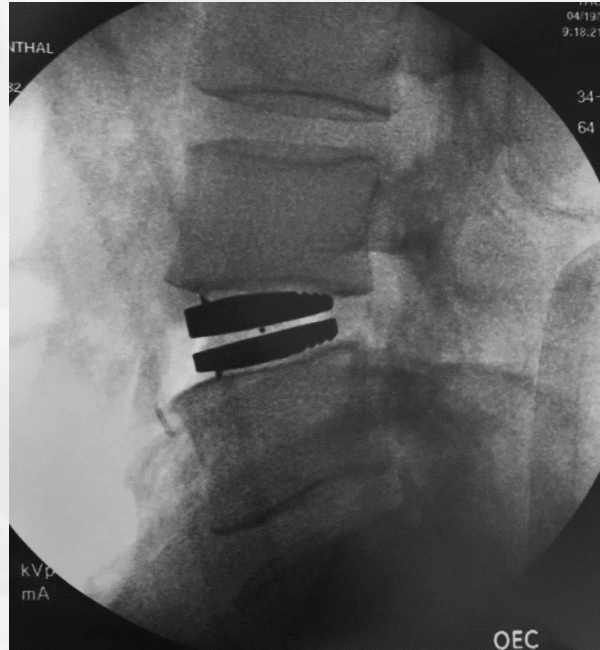
Number of TDR Cases by Surgeon:
2000 - 2018



FDA Study Experience

- **Charite**
- **activL**
- **ProDisc lumbar and cervical**
- **Kineflex lumbar and cervical**
- **Axiomed**
- **Mobi-C**
- **M6**
- **Flexicore**
- **Discover**
- **Neodisc**
- **Simplify**
- **Advent**

activL



M6



Reimbursement Landscape

Cervical

- **Covered by insurance: >90%**

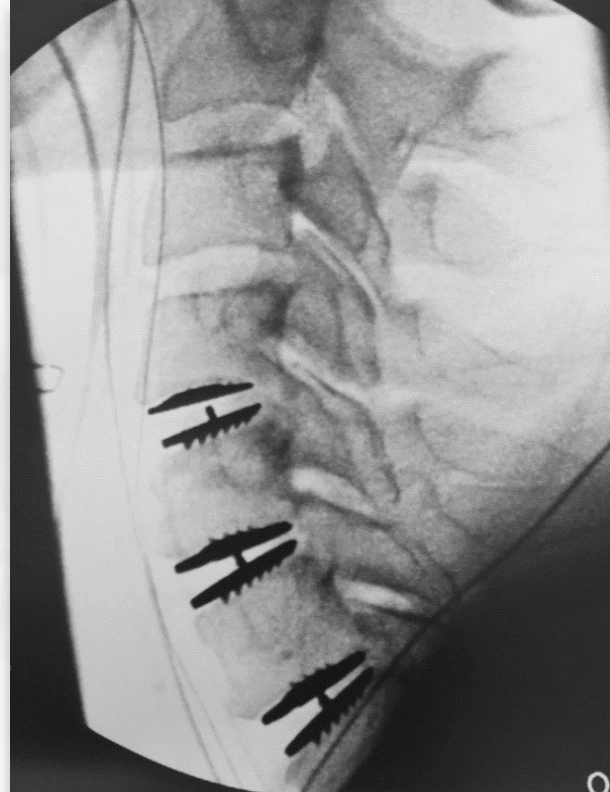
Becoming Gold Standard

Lumbar

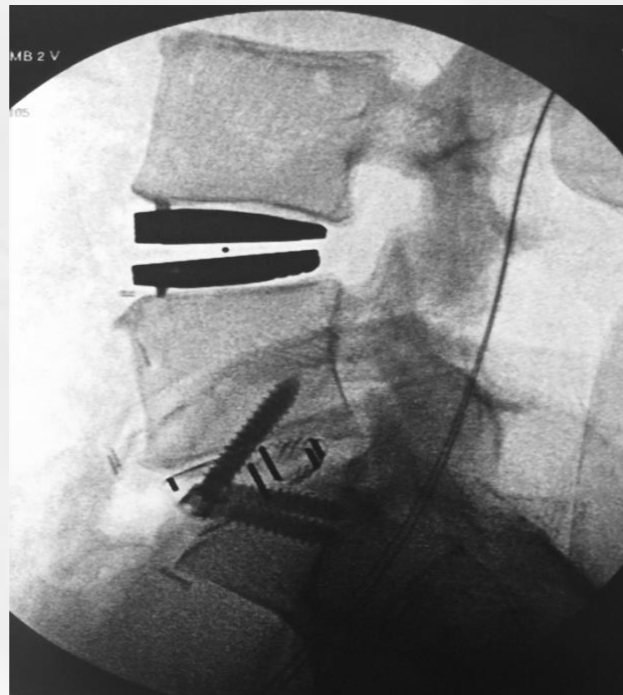
- Coverage: ~60%
- UHC eff. 9/1/18
- Still boutique product

“Off-Label” in US

Multi-Level



Hybrid



One Trick Pony



CDR Experience

Cervical-20% fusions

Lumbar-50% fusions


Zero Profile Fusion



Marketing

?Direct to consumer

Marketing
...”if you’ve been told you need
a fusion, you might be a
candidate for disc
replacement” ...



**Lumbar
Center of Excellence**





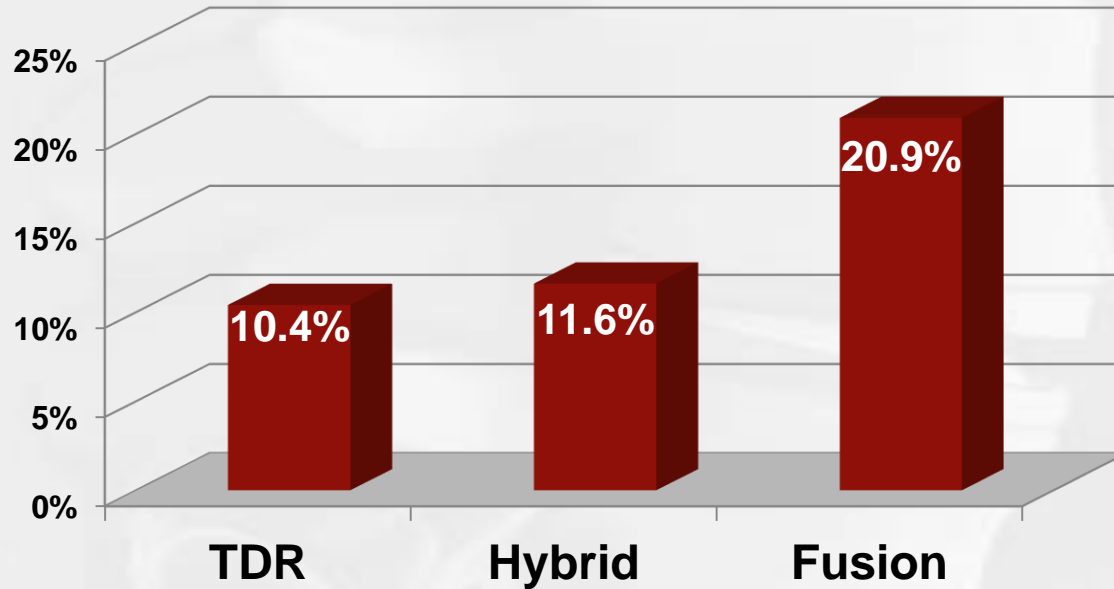
TBI Re-operation Experience

- **ALL re-operations were reported including those for wound infection and spinal cord stimulator implantation**
- **Patients undergoing surgery <24 mo prior to this report were excluded**
- **Longest follow-up was 134 mo**

TBI Re-operation Experience

- **Consecutive series beginning with 1st TDR case in 2000**
- **Included all TDR pts at least 2 yrs post-op and all pts who were fusion controls in randomized FDA IDE TDR trials**
 - **1,058 TDR**
 - **112 hybrid**
 - **67 fusion**

Re-op Rates by Surgery Type



TDR significantly lower than fusion ($p < 0.02$); trend for hybrid < fusion ($0.05 < p < 0.08$)

Analysis of Lumbar Total Disc Replacement Removals/Revisions during a 17 Year Experience with 1,707 Patients

**Scott L. Blumenthal, M.D., Jack E. Zigler, M.D.,
Richard D. Guyer, M.D., Donna D. Ohnmeiss, Dr.Med.**

**Center for Disc Replacement at Texas Back Institute
and the Texas Back Institute Research Foundation**

Results

- **Based on 1,707 lumbar TDR patients:**
 - **Removals: 0.99% (17 patients)**
 - **Revisions: 0.17% (3 patients)**
- **Based on 2,023 TDR devices implanted:**
 - **Removals: 0.89% (18 devices)**
 - **Revisions: 0.15% (3 devices)**

Complications Associated with the Anterior Approach to the Lumbar Spine: Analysis of 2,881 Consecutive Cases during a 6-year Period

**Scott L. Blumenthal, M.D.,
Jack E. Zigler, M.D., Jennifer Shivers, P.A.,
Richard D. Guyer, M.D., Donna D. Ohnmeiss, Dr.Med.**

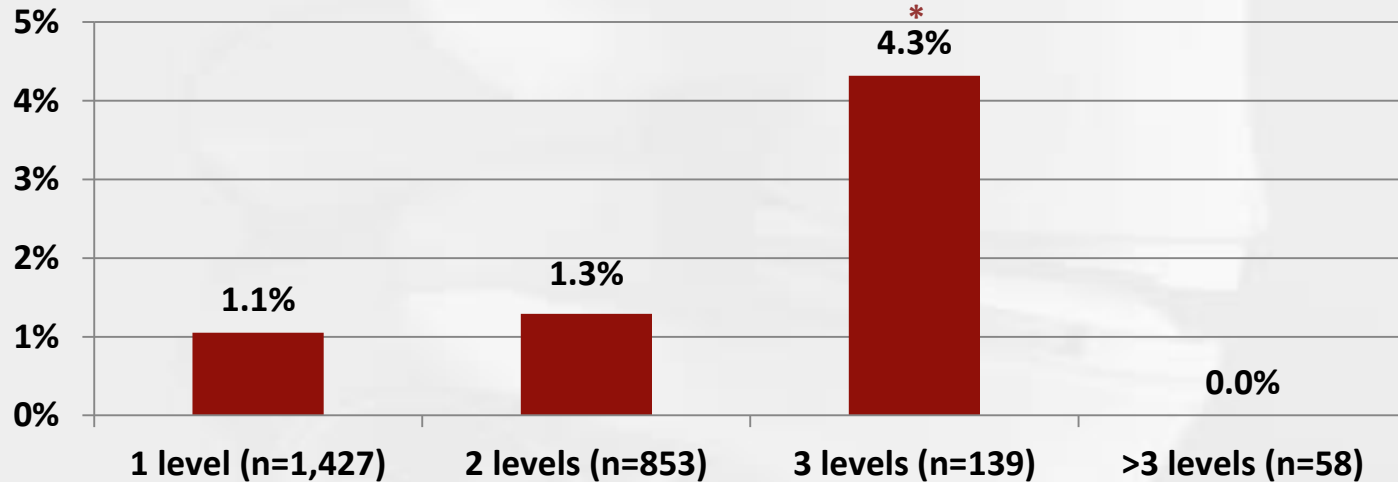
Methods

- **Consecutive series of 2,881 pts who underwent anterior lumbar spine surgery**
 - **6 yr period: Jan. 1, 2009 – Dec. 31, 2014**
- **All cases performed by spine surgeons associated with a multi-site spine specialty clinic**
- **Access surgeon used in almost all cases**

Results

- Overall occurrence of anterior approach related complications was 1.32%
 - 38 incidences in 2,881 cases
 - 31 vascular injuries (1.08%)
 - 5 bowel/bladder complications (0.17%)
 - 1 peritoneal injury (0.03%)
 - 1 rectus sheath hematoma (0.03%)
 - No deaths

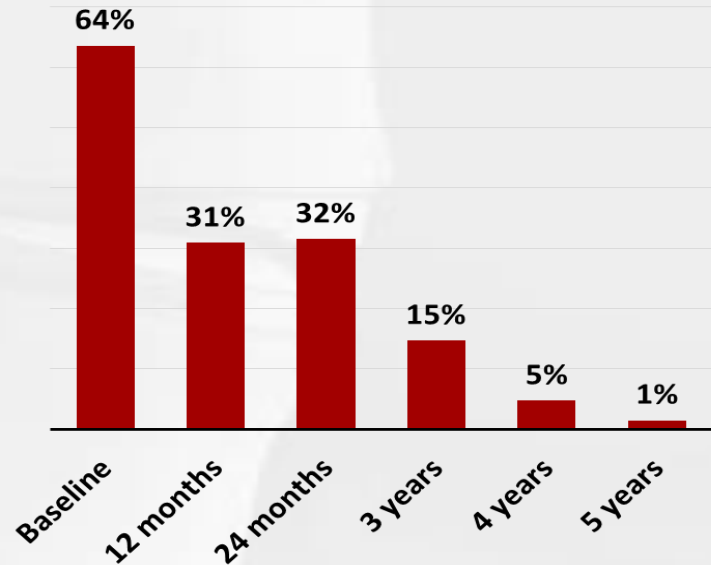
Approach Related Complications and the Number of Levels Operated



* Significantly greater than 1 or 2 level (too few in >3 group for meaningful comparison)

Narcotic Use

- The percent of patients using narcotics significantly decreased following TDR surgery
- By year 5, only 1% of TDR patients were using narcotics
- There were no differences in narcotic use between devices implanted



Surgical Pain Management at TBI/THCDS

- Reviewed current protocols to determine if changes could be implemented to reduce opioid use during hospitalization and post-op
- Strategy of using more muscle relaxers, anti-inflammatories (for appropriate surgery types), Gabapentin, etc. for pain management
- Shift from IV to oral when possible

Presurgical Psychosocial Screening at TBI

- **Psychologist communicates any concerns to surgeon prior to surgery**
 - Existing dependence or high risk of dependence
 - Possible challenges with weaning patient off of pain meds
 - Potential impact of dependence on surgical outcome
 - Suggest how to address dependence

New Protocol

- **Applies to:**
 - 1- and 2-level cervical TDR
 - 1-level lumbar TDR
 - Lami/disc
 - Decompression +/- Coflex
 - 1-level ALIF or 360 fusion



**Analysis of Hospital Length of Stay Following Lumbar
Anterior/Posterior Combined Fusion:
Is There a Disadvantage Associated with Shorter Stays?**

**Emily Putney, D.O., Scott L. Blumenthal, M.D.,
Richard D. Guyer, M.D.,
Jack E. Zigler, M.D.,
Donna D. Ohnmeiss, Dr.Med.**

**Spine Society of Australia
Melbourne
2016**

Results: LOS

- **LOS**
 - **DC'd day after surgery: 40.3%**
 - **DC'd after 2 nights: 51.4%**
 - **DC'd after ≥ 3 nights: 8.3%**

New Protocol: Pre-op

- **Pre-op (altered for specific procedures, patients with allergies, etc.)**
 - **Celebrex (not for fusion pts)**
 - **Gabapentin**
 - **Acetaminophen IV**

Protocol: Discharge Meds

- Discharge meds (altered for specific procedures, patients with allergies, etc.)
- Celebrex (not for fusion pts)
- Aleve (cervical TDR only)
- Flexeril
- Tramadol

Impact of New Protocol

- **Reduced use of PCA (most patients not use at all)**
- **Reduced discharge prescriptions of hydrocodone:**
 - **From average of ~90 to ~60**
 - **No increase in calls to office or ER visits for pain control**
 - **No increase in number of patients receiving refills at early follow-up visits**



THE GOOD THE BAD AND THE UGLY

Summary

- Consistent data from 4 continents up to 15 yr follow-up studies
 - Safety
 - Superior to
 - TDR similar or less than fusion

What more evidence is needed?

Fusion

- **Cigna – Must have all 4 of the following:**
 - **Unremitting pain and significant functional impairment after 6 consecutive months of exercise, analgesics, OT, lifestyle modification**
 - **Single-level DDD**
 - **Clearance from psych**
 - **Not smoking**

Fusion

- **“Aetna considers lumbar spinal fusion experimental for degenerative disc disease...”**
- **BCBS TX “lumbar spinal fusion surgical procedures are considered medically unnecessary if the sole indication is ...DDD...”**

TDR

- **More difficult to get insurance approval than for fusion**
- **Maybe?**

aetna

Clinical Policy Bulletin:
Intervertebral Disc Prostheses

Revision Info - 11/10/2006

This CPB has been revised to reflect the results of the ProDisc-L Total Disc Replacement (TDR) clinical trial. The trial evaluated the safety and effectiveness of the ProDisc-L TDR in patients with degenerative disc disease (DDD) of the lumbar spine. The trial results showed that the ProDisc-L TDR was safe and effective for the treatment of DDD in the lumbar spine.

aetna

Clinical Policy Bulletin:
Intervertebral Disc Prostheses

Number: 0591

II. Aetna covers the use of the ProDisc-L TDR (and the ProDisc-L Total Disc Replacement) for all other indications.

**Was this reversal driven by large quantities of data questioning safety or effectiveness?
No, simply bought by another company**

- 2006 Aetna coverage to include lumbar TDR
- By 2014, Aetna considered it investigational

TDR

- **UHC finally covered (threat of lawsuit) but made up new criteria**
 - **Lumbar ADR: No previous surgery.....and must have Modic changes!**
 - **Overtured by letter from CDR docs**

Anthem

REQUIRES Spondy!

**As a Profession,
Have we done this to ourselves?**

The Ugly

GET

Are you tired of living with chronic neck and back pain? The simple things in life again like going to work, playing with our minimally invasive procedure. Laser Spine Institute has helped more than 100,000 patients get their lives back again.

ADVANTAGES OF LASER SPINE INSTITUTE:

- No lengthy recovery*
- 97 percent patient satisfaction
- 99 percent patients recommendation rate as best

COMMON CONDITIONS TREATED:

- Spinal stenosis
- Degenerative disc
- Pinched nerve
- Bulging disc

TREATMENTS

...such as the bone marrow. They release signals that the body has suffered some type of injury. Platelets are a trigger. Like a soldier that needs orders, stem cells release platelets - tiny blood cells that help your body form clots to stop bleeding - to the injured site. Once there, platelets release proteins to regulate the inflammation and stimulate new cell growth. Stem cells then begin to change into the same type of cell that was damaged to help with healing. Unfortunately, the number of stem cells in human beings begins to decline shortly after birth. This reduction is the reason our bodies experience wear and deterioration as we get older - the fewer stem cells lead

Message

Back to...the outdoors!

Call Us 24/7 855.765.4022

FREE

Alternative to surgery

Back pain with a... and... picture.

...surgery in the world... looks at back surgery from all... require nothing more

...you can get

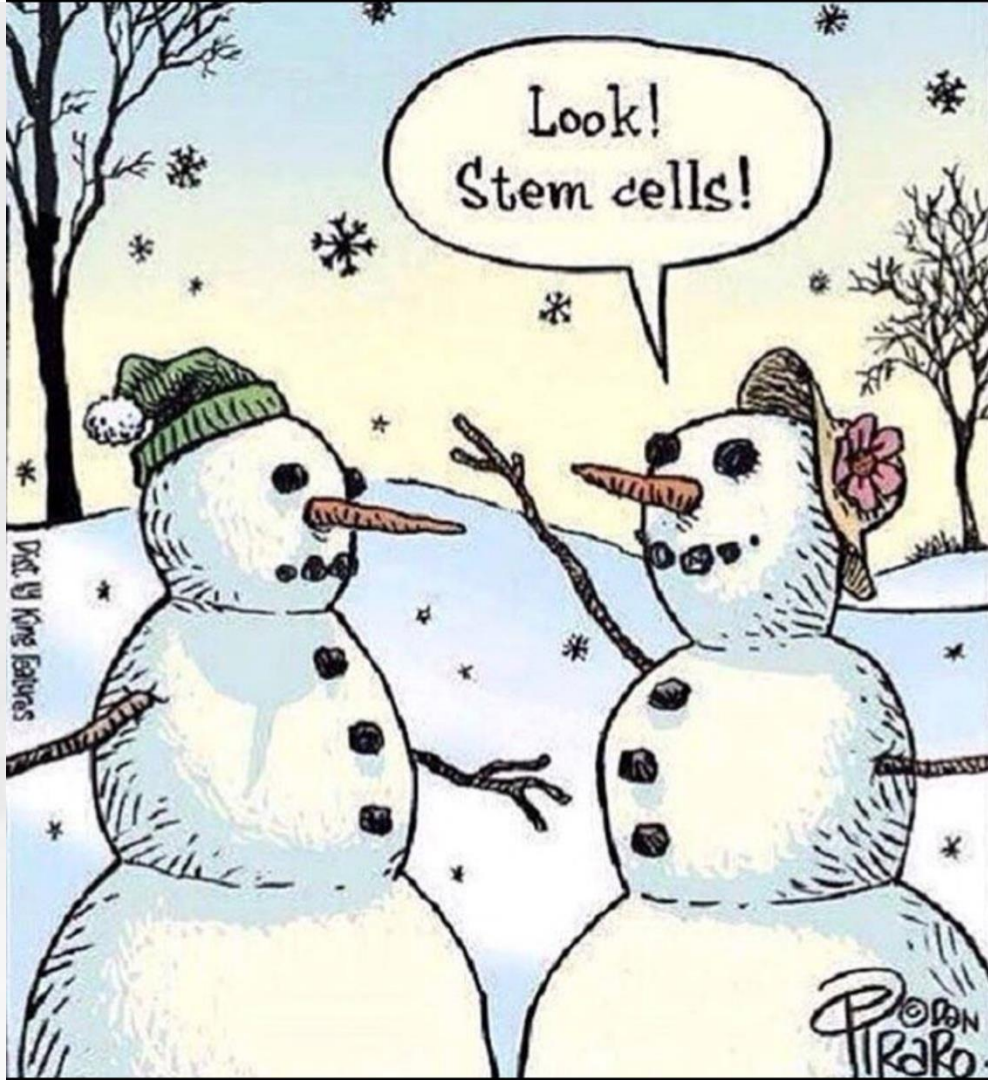
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...son risks

Great Marketing, No Evidence, Questionable FDA status in some cases



What About Cost?

- **Assumption: New technology is always more expensive**
- **But, look at the data!**

Lumbar TDR Costs Studies

- **Several studies compared TDR to fusion**
 - **Methods included economic modeling** ([Guyer et al, 2007](#)), **randomly selected patients and averaged database charges/costs** ([Patel et al, 2008](#)), **IDE trial patients** ([Leven et al. 2007](#)), **and national data registries with unmatched comparison groups** ([Kurtz et al, 2010](#)), **cost data for a patient series** ([Stubig et al, 2017](#))

Lumbar TDR Costs Studies

- Although the methods used in the studies varied greatly they all found **TDR was less expensive** than fusion with the one exception of a cost model for ALIF with autograft only which is rarely used today

Costs of Cervical Disc Replacement *Versus* Anterior Cervical Discectomy and Fusion for Treatment of Single-Level Cervical Disc Disease

An Analysis of the Blue Health Intelligence Database for Acute and Long-term Costs and Complications

Kris Radcliff, MD* Jeff Zigler, JD† and Jack Zigler, MD‡

- **Insurance industry data generally unavailable**
- **Blue Health spun off as a for-profit venture by “the Blues”, allowing access to payment database**
- **Allowed authors to “work backwards” from payments to clinical events (post-op, peri-op, and pre-op) by CPT and ICD-9 codes**

Total Costs: TDR ~ 12% Lower

	TDR	ACDF
Index event	\$20,722	\$22,379
Index event + 90 day global post-op period	\$22,761	\$25,029
Discharge to 6 wks	\$791	\$1,236
6 wks to 3 mos	\$1,216	\$1,497
3 to 6 mos	\$2,147	\$2,631
6 to 12 mos	\$4,127	\$4,566
12 to 18 mos	\$3,106	\$3,914
18 to 24 mos	\$2,862	\$3,596
24 to 36 mos	\$3,753	\$4,806
36 to 48 mos	\$1,040	\$1,526
TOTAL	\$34,979	\$39,820

Cervical TDR Based on “Blues” Insurance Data

- “Real world”, single payor data
 - Outside of a study
- TDR was effective in reducing the monthly cost of care compared to ACDF
- TDR patients had lower re-op rates than ACDF patients

Potential Cost Benefit of TDR

- **No potential for “add-on” costs:**
 - **Anterior plates**
 - **Interbody devices**
 - **Various combinations of bone graft materials including BMP**
 - **Posterior instrumentation**
 - **MISS screws**
 - **Facets screws**



Thank You