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Or Where Are We in 2015?

Disclosures
• AO Spine
• Benvenue Medical
• EBI
• Globus Medical
• Intrinsic Therapy
• Johnson & Johnson, DePuy Spine
• Magnifi Group
• Medtronic
• NuVasive, Inc.
• Samumed
• SI Bone, Inc.
• Spinal Kinetics
• Stryker
• Symmetry
• Vertiflex

Acknowledgements
Gunnar Andersson, M.D., Ph.D.
Robin Young
Cary Hagan
Michael Hubbard
Spine Fusion Growth

Growth in Key Procedures for Musculoskeletal Care

Spinal fusions ↑↑ 67%? But what else?

Motion Preservation

? Gone for now?

Artificial Discs

- Worked fine (?L5-S1?)
- Outcomes = Fusion (The goal of the FDA studies) ["no less than"]
- Complications / Recovery < Fusion
- Literature / RCTs → support use
<table>
<thead>
<tr>
<th></th>
<th>Lumbar TDR</th>
<th>Cervical TDR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>700+ articles/abstracts</td>
<td>300+ articles/abstracts</td>
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</table>

Almost all Good - Excellent
Many RCTs

**Lumbar**
- FDA approves
- NASS fights against its' use
- Insurance will not pay
- Not used

**Cervical**
- FDA approves (a few companies)
  (Companies sue each other)
- NASS fights against its' use
- Only a few insurances pay
- Limited use
Nucleus Replacement

Nucleus Replacement Options

Mechanical

• PDN – Raymedica  Off Market
• Neodisc – Nuvasive  Off Market (no sales)
• NeuDisc – Replication Medical  Didn’t get past trials
• Regan – EBI  Off Market
• Nubac – Pioneer  On the shelf
Injectables

- Injectable Hydrogel (Nucore)  ▪ Off Market
- Biocompatible Polyurethanes & Containment Balloon (Dascor)  ▪ Company Closed

Annular Repair

- Mechanical
- Biologic
  ▪ Primary
  ▪ Sealant
  ▪ Ingrowth

- Biologics  ▪ Off market
- Mechanical
  ▪ Long, slow trials
  ▪ New companies trying
Dorsal Arthroplasty

Device Spectrum

- Some approved
- But poor / limited use
- Many explanted, or failed
- Many companies closed

Flexible “Rods”

(Approved as Fusion Devices)

(LOL) ↓↓ (😊)

FDA: Extended market surveillance to see if fusing
Facet Arthroplasty

Almost all off market or
Company closed

What is new Now?

Spine Technology Awards 2014 (R. Young)
Top Ten New Spine Technologies 2014

R. Young

MAGNIFUSE II

Skin Closure provides a non-adherent alternative to staples, sutures and glue for surgery and incisional closure.

ZipLine Medical Inc.
Lessray is an image enhancement platform designed to take low quality, low radiation images and improve them to look like conventional full dose images.

SafeRay Spine, LLC

Scolioscreen

A medical device to be used in collaboration with smartphones for the early detection of spinal deformities such as scoliosis.

Spinologics, Inc

G-Arm Multi-Plane Surgical Imaging

Whale imaging provides bi-plane views and allows both AP/LAT anatomy to be viewed simultaneously to help surgeons plan.
109 Design

"Smart" strap that replaces the existing straps of a scoliosis brace. These straps can measure how long and how tightly the braces are being worn and then send the real-time data to a smartphone application using Bluetooth Low Energy.

Smart Strap

Aesculap, Inc

Direct visualization through an endoscope. No radiation.

S4 Element MIS

MySpine Patient Matched Technology

Low dose patient CT scans and engine algorithms to create patient-specific anatomical drill/screw placement guides to simplify pedicle screw placement during spine surgery.

Medacta International SA
It is comprised of two sub-sets: the single-use SafeAccess pedicle access, consisting of a full arm of heights and diameters, and a set of reusable instruments.

**ABC Pedicle Screw System**

**SafeWire, LLC**

*Pedicle Access Needle with Broach* is designed to improve the surgeon’s workflow, depth accuracy, and reduce the need for fluoroscopy when accessing the pedicle.

**Tiger Express**

**Vital S, LLC**

*Dual Function Directional catheter*, *ReLeaf Anesthetic Delivery Catheter*.
Spinal Robotics

Summary

- Prospective RCT: 95% Accuracy
- European Spine Journal 2013
  - Reduced 21% stay
  - 96% accuracy
- Reduced complication rates by 48%
- Reduced re-operations 44%
- Reduced average length of stay 27%

Other area Robotics
Carving Out Space with Niche Procedures

But: With Hefty Price Tag:
Eg: MAKO—Success Depends on Growth of their UKR, MI Hip

Projected National Volumes of
MAKO-Eligible Procedures

630
Estimates intake of new
patients needed to cover
capital costs of MAKO RIO.

5727
Estimated return on
investment based on
national volume rates and
return on investment.

Diagnostics

MR Spectroscopy app for standard high field MR scanners to:

- Image chemical signatures of disc pain via non-invasive MRI+8 exam
- Assist doctors to non-invasively diagnose painful discs
- Improve current dx regimens for DLBP, supplement MRI, replace discogram
- Support new and expanded clinical utility-based dx
- Leverage insights to new dx across a range of neuro-imaging

GOOD
"Personalized" Technology

NO Game Changers Here
Just “Add-Ons”
(Except for Diagnostics and maybe “Personalized” / Automated Implant Technologies)

Conclusion
- Regulations are killing major innovation at a time when it is needed most...
- Development should focus on "unmet clinical needs" without being bound by reimbursement considerations...
- Major advancements are not occurring because of the tough conditions which results in only small steps forward...
Small Companies Deliver Innovation

- U.S. Start-Ups are Innovation Engines
  - 97% of medical device manufacturers have < 100 employees
  - Collaboration of researchers, physicians and corporations

U.S. Medical Device Manufacturing Companies by Number of Employees

Source: FDA, CDRH

Innovation Dilemma... Investors Avoid:

- PMA projects
- Projects requiring new reimbursement codes

Small Companies (Spine) Nearing Extinction

- Investment in Devices down by 42%
- Investment in Ortho-Spine has been reduced by 58%
Result: Incrementalism

- Only small improvements to existing technologies are possible (510K)
- US regulatory & reimbursement challenges have nearly eliminated available capital from investors due to:
  - Regulatory costs/uncertainty
  - Forced clinical trials overseas
  - Delayed reimbursement
  - ? Reimbursement ??
    - Insurance
    - NASS

Tough Regulatory Environment

Highly uncertain process stifling innovation

- Improving, but lengthy, approval timelines
- 2/5 of small MD&D companies receive EU clearance first*

* Source: Northwestern Univ. survey of 356 med device manufacturing reps and regulatory affairs professionals

Metrics: FDA Rejections

- Reduction in IDE studies and PMA approvals

Source: Makower, et al. November 2010, FDA Impact on Medical Innovation
- 40% decrease in IDE Approvals
- 60% decrease in PMA Approvals
**Metrics: EU vs US Delay**

Add delay in the reimbursement processes (~4 years)

C. Hagan

**Decreases in Healthcare spending**

**Structures and incentives aligning for change**

- Hospitals increasingly driving decisions
  - Hospital ownership of practices growing, hospital consolidation, centralized purchasing
- Incentives to reduce costs, increase economic value
  - ACO's, shared savings, bundled payments, economic value
  - CMS “Next Generation ACO Model”

*Chart source: Accenture, “Clinical transformation: New business models for a new era in healthcare”*

**Medicare reimbursement cuts**

*ACA’s Medicare Fee-for-Service Payment Cuts*
High Deductible plans

Annual Deductibles of Individual Plans Selected on eHealth
October 2013 – March 2014

10,000+
8,000-10,000
6,000-8,000
4,000-6,000
2,000-4,000
< 2,000

Source: Advisory Board Orthopedic and Spine Market Trends Apr 2014

Changing Point of Sale

Surgeons becoming less influential

- Trend toward centralized purchasing
- General Purchasing Organization (GPO) contracts account for ~73% of non-labor hospital purchases

Value of Care to Drive Orthopedic Policy

Shifting Imperatives for Measuring Value

Quality of Outcomes
- Patient input
- Outcomes
- Functional

Cost Conscious Care Delivery
- Value of precision technology
- Surgical vs. conservative care

Financial Incentives Tied to Quality

Clinical Results
- Patient Perception

Source: Advisory Board Orthopedic and Spine Market Trends Apr 2014

50

Anticipated GPO usage by hospitals*

2003 2011

Increase
Decrease

- Source: K.E. & L.E. Consulting
- Breakaway Policy Strategies, "Eight Million and Counting: A Deeper Look at Premiums, Cost Sharing and Value of Premium Technology"
NEW TECHNOLOGY DEVELOPMENT

<table>
<thead>
<tr>
<th>DECISIONS/INFORMATION</th>
<th>INDUSTRY</th>
<th>PROFESSION</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is needed?</td>
<td>??</td>
<td>xx</td>
</tr>
<tr>
<td>What technology is available or coming?</td>
<td>xx</td>
<td>??</td>
</tr>
<tr>
<td>Patients to assess/access</td>
<td>0</td>
<td>xx</td>
</tr>
<tr>
<td>Protocol (study/development)</td>
<td>x</td>
<td>xx</td>
</tr>
<tr>
<td>Money for clinical (or basic) research</td>
<td>xxxx</td>
<td></td>
</tr>
<tr>
<td>Presentations (papers)</td>
<td>xx</td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td>xx</td>
<td>xx</td>
</tr>
<tr>
<td>Marketing</td>
<td>xx</td>
<td>+/-</td>
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Idea
Design on Paper
Worthwhile?
Investors + Physician Panel
Device or Drug
↓
S.A.B.
↓
Protocol
↓
Trials
↓
Presentations
↓
Publications

FDA
↓
Medicare + Insurance
↓
Sales
↓
Education

INVESTORS want one thing
S.A.B.  
**want rewards**

- Involvement in study
- Presentations
- Publications
- Prestige
- Patient care improvement
- Solve a clinical problem
- Consulting time fees
- Stock options

Presentations/Publications  

**DISCLOSURES**

Is that enough?

Is it valid?

Is what you hear/read the real truth?

**CLINICAL RESEARCHER**

If ☑️: want rewards (early phase)

Developers/SAB: want academic recognition

**BUT**

Clinical studies should be by others not rewarded financially

Who will do that work?
INDUSTRY

Aware of conflicts
Sales
Stay “clean”
  But promote
Sell
Get studies done and published

Publication/Presentation

Disclose Financial Associations
  Taints Study
  Why?
  Who else would do early?
  Who else cares early?

But

If not invited into trials early
  Mad
  Angry
  Denigrate studies
N.I.H. Funding

Publications any cleaner?
Any less “tainted”?
(Need to publish something)

N.I.H.

Easily accepted
No boxes to check
“Pure”

But is it?
How do you get refunding?

Negative results?
or
Positive results?

Do you return the money if negative?
Put a positive “spin” on the results?
Publish negative Results?
INDUSTRY FUNDED STUDIES REPORT POSITIVE RESULTS MORE OFTEN THAN NON-INDUSTRY

Non-industry studies
50% neutral results

Industry funds
only 20% neutral results

Shah, Alberts, Vaccaro
Spine 2005

However

Early clinical trials in limited patients too few with too short follow-up for publication

This leads industry and M.D. to pursue larger enrollments – with positive results anticipated (and known from trials)

*So should be positive*

If early results negative, the project would be dropped

And

If results of clinical trial poor and project (implant-drug) dropped –

Why publish it?
Who would care?

Maybe these are the reasons studies are mostly positive
But

Any publication for N.I.H. (or non-industry funding)
Is worthwhile -
for personal CV
So neutral (often non-helpful) findings are OK

Is the relationship “tainted”?
Is it over blown?
Are only those uninvolved pure?

AAOS News

• Physicians who become involved in the business side of medicine – as inventors, educators, or consultants – must do so carefully and ethically, placing their responsibility as healthcare providers over financial gain.
Total Biomedical Research Funding (U.S.)

1994  $37 billion  
2003  $94.3 billion

57% Industry (↑ over time)  
28% N.I.H. (↓↓↓ over time)

Medical Product Co.

• 58% total US research funding  
• 70-80% worldwide from US companies

But Real $$ going down

Funding

<table>
<thead>
<tr>
<th>Year</th>
<th>NIH/NIAMS</th>
<th>Priority Score</th>
<th>For Orthopaedics</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>$499,417,000</td>
<td>154</td>
<td>$126,680,000</td>
<td></td>
</tr>
<tr>
<td>2005</td>
<td>$507,755,000</td>
<td>150</td>
<td>$114,000,000</td>
<td></td>
</tr>
<tr>
<td>2007</td>
<td>$507,292,000</td>
<td>144</td>
<td>$50,247,620</td>
<td>($36,255,716)</td>
</tr>
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Now

(NIAMS: Arthritis/Bone-Muscle/Skin)
NIH Funding

- ↓ 2% in 2008
- ↓ 8.6% 2003 → 2007 (inflation adjusted)

JAMA Jan 13, 2012

NIH

Decreasing funding
Increasingly rigorous and difficult

Industry

Decreasing innovative product funding
↓ ↓
Increasing scrutiny
R&D Spending

<table>
<thead>
<tr>
<th>Year</th>
<th>Annual Sales</th>
<th>$ for R&amp;D</th>
<th>R&amp;D as % of Sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>1.6 billion</td>
<td>$98 mil</td>
<td>6%</td>
</tr>
<tr>
<td>2014</td>
<td>1.9 billion</td>
<td>$129 mil</td>
<td>7%</td>
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But what is in R&D?

FDA

“Beat the Gold Standard”

“No worse than” no longer works

Proven medico-economic benefit

But have to do the studies to decide

Very long

Very expensive

Very challenging

Future Treatment

Biology > > implants

Long term studies

How long follow for biologic consequences?

$ Who funds $
And Now This

e.g.: Challenges:
Standard device trying to get into existing FDA cleared and Medicare coded market
Trial protocol not approved and updated by FDA
Locally sponsored study, won’t appeal to FDA
Biologic: Small molecule injected into disc, affects degenerative process

Phase I: FDA requirements:
Females: None with child bearing potential;
Males: must abstain or wear protection for 12 months

Could you predict this???

RCT’s 2 year follow-up for publication/FDA
Who supports?
Who follows?
Who collects data?
Who reports?
Multi-center co-ordination?

How “clean” is enrollment in surgical trials?

Who Funds?

• Private M.D.
• Universities
• Developer/VC
• Medical Societies
• Industry

Going overseas cheaper, easier, quicker
The Company-Physician Partnership

From the legal perspective

The relationship between industry and physician is critically important.

Companies cannot develop and introduce new and useful technologies in a vacuum -- need practical input from physicians.
Physicians’ inability to interact fully with companies will delay, potentially indefinitely, the introduction or improvement of technologies.

The relationship between industry and physicians is increasingly scrutinized

- Subpoenas to orthopaedic and cardiac companies, investigating potential violations of U.S. anti-kickback laws based on company-physician relationships
- Adoption of restrictive codes and policies by governing organizations
- Prosecutions of Drug companies
- Eroding public trust in the medical industry due to recent
  - malfunctioning products (pacemaker recalls)
  - malfunctioning drugs (Vioxx)
  - corporate scandals

US government has subpoenaed records from every orthopaedic company to determine if

Any company has broken the law in collaborating with surgeons by providing “money” – (not appropriate compensation)
Biomet, DePuy, Smith & Nephew, Zimmer

2002-2006
- $800 million on 6,500 consulting agreements

2007
- Settled with US Government
- $310 million + Government supervision
- (also Stryker and Wright)

Relationship Restrictions

- Laws (e.g., Anti-Kickback, False Claims)
- Professional Society Codes of Conduct (AdvaMed, AHA)
- Internal company codes and policies
- Hospital codes and policies (OIG guidelines)
- Contractual provisions between Industry/M.D.
- Sunshine ACT ($10)

CONSIDERATIONS

The stronger the relationship between company and M.D., whether through

prominence (senior advisor, technical, advisory board)
volume of business from M.D.
total consulting fees paid

the more likely the relationship will be subjected to scrutiny.
CONSIDERATIONS

If business is conducted, it must be documented

Companies cannot afford to risk their futures based on questionable demands of a few physician consultants

Physicians cannot afford to work with companies that overlook the existing restrictions

(and vice versa)

Ethical responsibility to set an example by all actions

THE OBVIOUS NEGATIVES?

Research presentations biased toward company product
(consultation fees, research/clinical support)

“Favorites” cannot be avoided.
The Institute of Medicine (IOM) of the National Academies' Committee on Conflict of Interest in Medical Research, Education and Practice has held at least three open hearings regarding industry relationships.

"This conflict of interest examination investigation looks broadly at medical research, education, as well as private practitioners, and the potential conflict of interest."

David Lovett, J.D.; AAOS

We believe that a collaborative relationship is necessary to improve patient care, but we also recognize that it must be carefully scrutinized to avoid pitfalls of improper endorsements either real or perceived."

David Rawling, M.D.; AAOS
Report from the Task Force on Surgeon-Industry Relationships in the Discipline of Orthopaedic Surgery

AAOS Now

- Before embarking on any consulting arrangement, physicians should test it against several considerations, including the following:
  - Does it violate the physician’s fiduciary duty to patients?
  - Does it require industry oversight and permission before research data is released?
  - Does it restrict use of competitors’ products that may be superior in efficacy?
  - Does it provide reimbursement for work not done?
  - Would the public exposure of the contract change the physician’s desire to continue it?
  - Does it violate any ethical standards a physician should hold dear?

NIH

- Research is based on scientific evidence, not inappropriate influences.
- As decision makers, senior researchers answer to a higher standard
- To remain at the forefront of science, interaction with industry, professional associations, and public health activities is necessary.
Conclusion
Not much change (2015)
Nothing exciting (game changing)
In near horizon

Financial Changes
Business Changes

For Spine Surgeons in 2015

Thank You