

SmartStim: Preliminary Report

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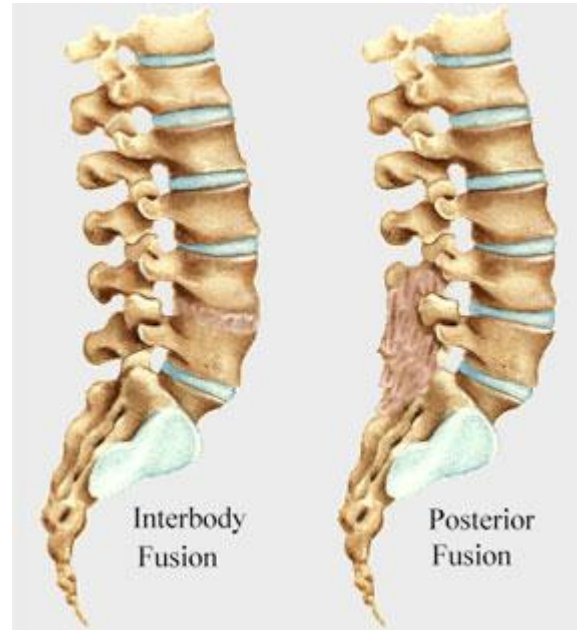
Problem: Pseudarthrosis

What is it?

- ❖ Fusion procedure complication
- ❖ Fractured bones do not fuse
- ❖ Bone graft failure

What causes this condition?

- ❖ Lack of bone growth
 - Influenced by many factors



Bone graft locations in spinal fusions → possible pseudarthrosis sites

Problem: Pseudarthrosis

Why is it harmful/detrimental?

- ❖ Severe chronic pain
- ❖ Spinal instability
- ❖ Second surgery
- ❖ National monetary impact

	FBSS	Rheumatoid arthritis	
Work disability rate	78%	50%	
Disability			
Oswestry Disability Scale ^a (mean)	56.4	27	
Health-related quality of life			
EQ-5D index ^b (mean)	0.16	0.42 to 0.752	
Short-Form 36 domains ^a (mean)			
Physical functioning	23.4	62.3	Note: lower values indicate greater disability rating
Role – physical	5.1	49.0	
Bodily pain	16.3	58.0	
General health	45.7	52.1	
Vitality	31.2	52.2	
Social functioning	35.2	70.3	
Role – emotional	36.4	72.3	
Mental health	52.7	69.2	



Problem: Pseudarthrosis

How often does it occur?

- ❖ Large variability
- ❖ ~9-18% spinal fusions
- ❖ ~2-12% long-bone fusions

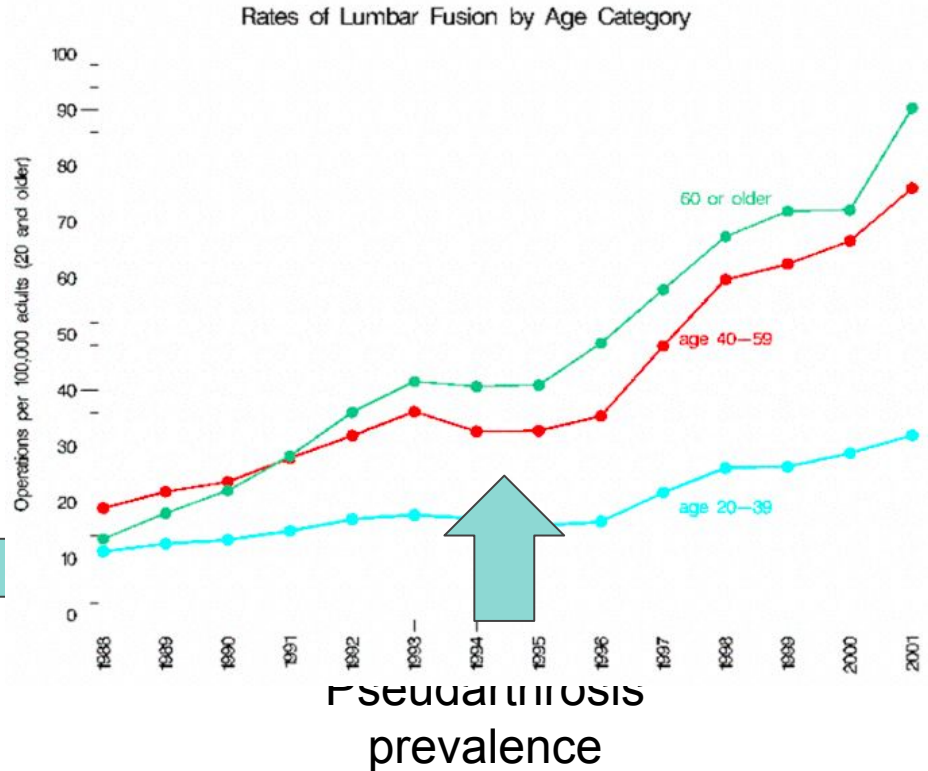
Problem: Pseudarthrosis

Is it pervasive?

- ❖ >400,000 annual spinal fusions
 - 137% increase 1998-2008
- ❖ ~40,000 long-bone fusions

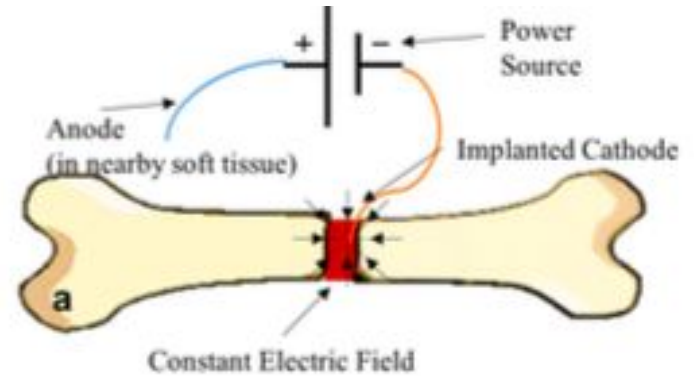


Fusion operations



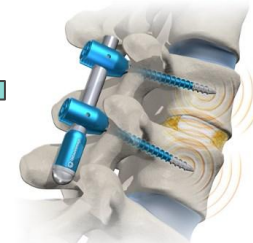
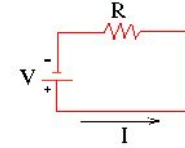
Solution: SmartStim

How would SmartStim combat pseudarthrosis?



Product Market

- ❖ No existing solutions like SmartStim
- ❖ Project scope:
 - Biocompatible power supply
 - Biocompatible microcontroller
 - Resorbable, steady current output circuit
 - Mechanical attachment to OsteoVantage pedicle screw
- ❖ Demand will increase as fusions increase
- ❖ Target market = orthopedic and neuro surgeons



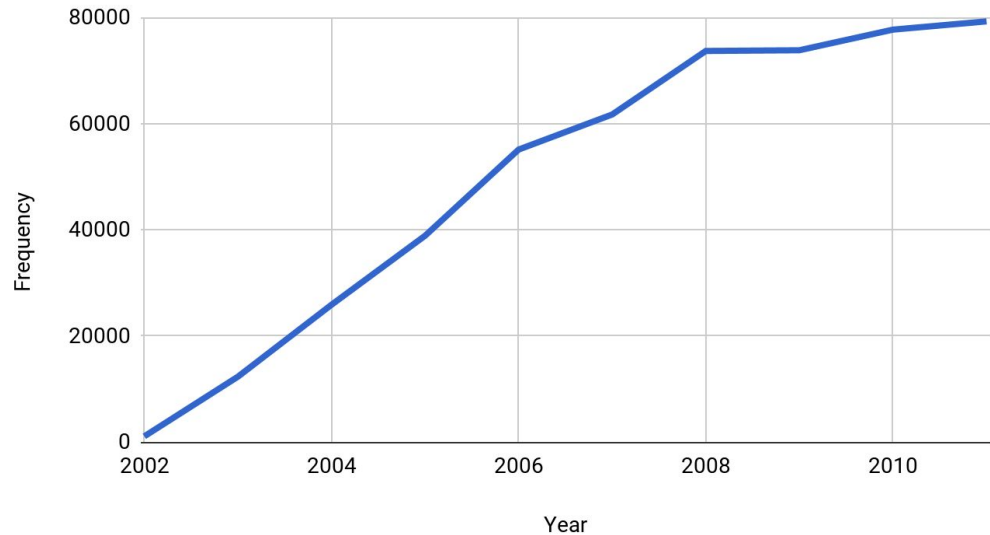
SmartStim



Existing Solutions: BMP

- ❖ Bone morphogenic proteins
- ❖ Only current precautionary measure
 - Gold standard
 - Increasing usage
- ❖ Costly
 - \$4,000-%6,000 per treatment
 - 11-41% hospital charge increase
- ❖ Poorly controlled in space/time

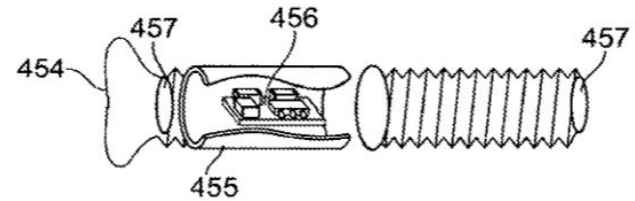
BMP Usage Since 2002 FDA Approval



Adapted from Source 9

Existing Solutions: Ultrasound Stimulation

- ❖ Circuit within larger screw
- ❖ Broad stimulating application
- ❖ Largely focuses on signal transducer
- ❖ Patent only, not on market



Existing Solutions: Biocompatible Power

- ❖ Dissolvable silk battery
- ❖ Electrolyte soaked, conductive silk between electrode plates
- ❖ 0.87 V for 45 minutes
- ❖ Duration proportional to silk layering?





Existing Solutions: Biocompatible Microcontroller

- ❖ No current solution
- ❖ Unpublished paper for wireless, programmable, two-channel nerve stimulator
- ❖ Altered output frequency
- ❖ No two-way communication
- ❖ Inaccurate current output control



Existing Solutions: Resorbable Stimulating Circuitry

- ❖ No current solution
- ❖ Client has utilized resorbable circuit for measuring intracranial pressure

Existing Solutions: Pedicle Screw Mechanical Attachment

- ❖ No current solution

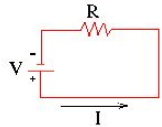




SmartStim Design Specifications

Design Specification	Metric
Current Output	5-200 μ A
Size	no larger than existing hardwire model
Lifetime of Power Supply and Circuitry	3-6 months
Addressability	wireless on/off, impedance check, and amplitude adjustment
Attachment	secured safely to existing OsteoVantage pedicle screw
Cost	no limit specified by client
Safety	biocompatible and resorbable materials, emergency addressable on/off mechanism, leak current <1 μ A

Team Organization and Roles



Microcontroller	All	
Steady current output circuit	Natalie N.	Natalie O.
Power solution	Natalie N.	Nathan
Mechanical attachment	Natalie O.	Nathan

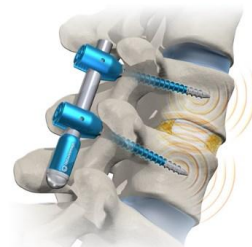
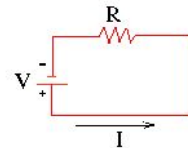
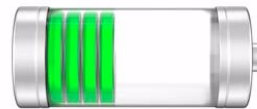


Product Timeline

	Oct. 1-7	Oct. 8-14	Oct. 15-21	Oct. 22 - Nov. 4	Nov. 5 - Dec. 2	Dec. 3-9
Preliminary Report Due	█					
Preliminary Report presentations		█				
Create web page			█			
Progress Report Due						█
Conceptual research and learning		█				
Design multiple potential solutions for each aspect					█	
	Dec. 10-16	Jan. 14- Feb. 24	Feb. 25 - Mar. 3	Mar. 4-10	Mar. 11 - Apr. 21	Apr. 22-28
Progress Report Presentations	█					
Verification Validation Report Due			█			
Verification Validation presentations				█		
Completed Prototype						█
Prototyping		█				

Summary

- ❖ SmartStim goal: decrease pseudarthrosis occurrences and severity
- ❖ SmartStim scope: 3 novel elements attached to pre-existing OsteoVantage screw
 - Prototype delivery April 23, 2018
- ❖ Questions?



SmartStim



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