SmartStim: Progress Report

TEAM 14: NATALIE NG, NATALIE ORR, NATHAN SCHMETTER

SmartStim Overview

Client

Why is it needed?

What does it do?

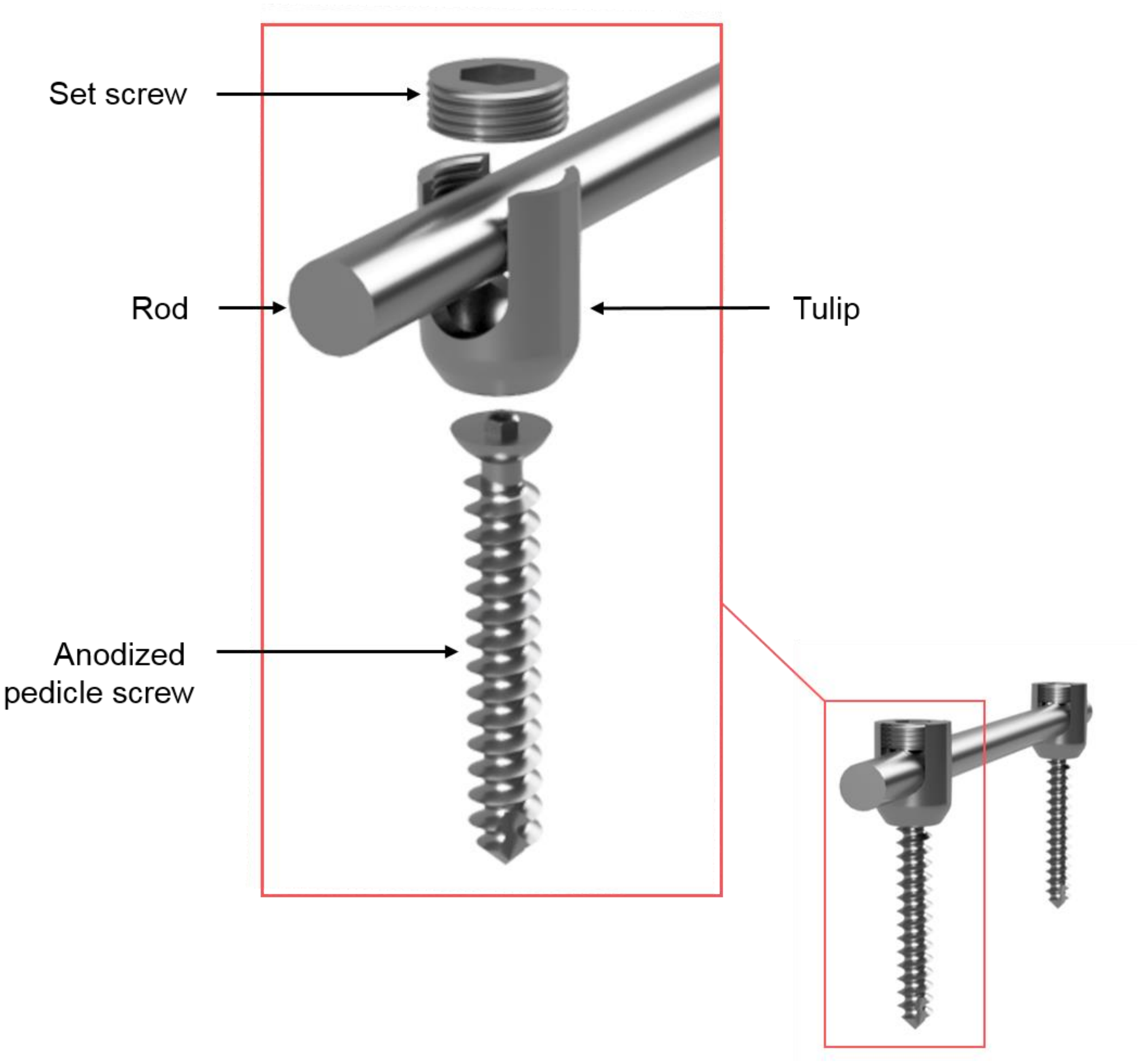
Client: Dr. Matthew MacEwan, OsteoVantage

Need Statement: There is a need for the development of a subcutaneous device to safely decrease instances of **pseudarthrosis** in patients of bone fusion surgeries.

What it does:

SmartStim Overview

The components of the existing mechanical system



SmartStim Overview

Surgical implementation of the mechanical system

Changes to Preliminary Report

- Design specifications
- Design schedule
- Team responsibilities

Design Specification	Metric
Addressability	Wireless on/off, impedance check, & amplitude adjustment
Attachment	Secured safely to existing OsteoVantage pedicle screw with minimal number of expose wires
Cost of R&D	< $500
Current Output	5 – 200μA
Ease of Use for Surgeon	Adds < 5 minutes and minimal difficulty to existing procedure
Lifetime	> 6 months
Patient Compliance	No pain or discomfort, requires charging with a maximum frequency of weekly
Reproducibility	Can be produced and utilized for a wide variety of patients; minimal dependence on size or spacing of vertebrae.
Safety	Biocompatible and/or resorbable materials, emergency on/off mechanism, < 1μA leak current
Size	No larger than existing model used in rat studies
Transience*	Should not resorb in less than 12 months, but should fully resorb within 24-36 months

Altered specification

New specification

Changes to Preliminary Report

- Design specifications
- Design schedule
- Team responsibilities

Design Schedule: Complete circuit prototyping by the end of February to allow 4-6 weeks for minitiurization / speciality fabrication and subsequent animal studies.

Team Responsbilities:

- Less strict division of labor → shared responsibilities
- Nathan has taken lead role on lead role of client communication

Shared	Natalie N.	Natalie O.	Nathan
• Weekly logs • Website maintenance • Mechanical attachment design	• Progress presentation • Power solution research and design • Steady current output circuit design • Electrical connection via mechanical attachment	• Preliminary presentation • Steady current output circuit design • Preliminary verification & validation studies	• Verification & Validation presentation • Client communication • Power solution research and design • 3D modeling of mechanical attachment

Design Alternatives

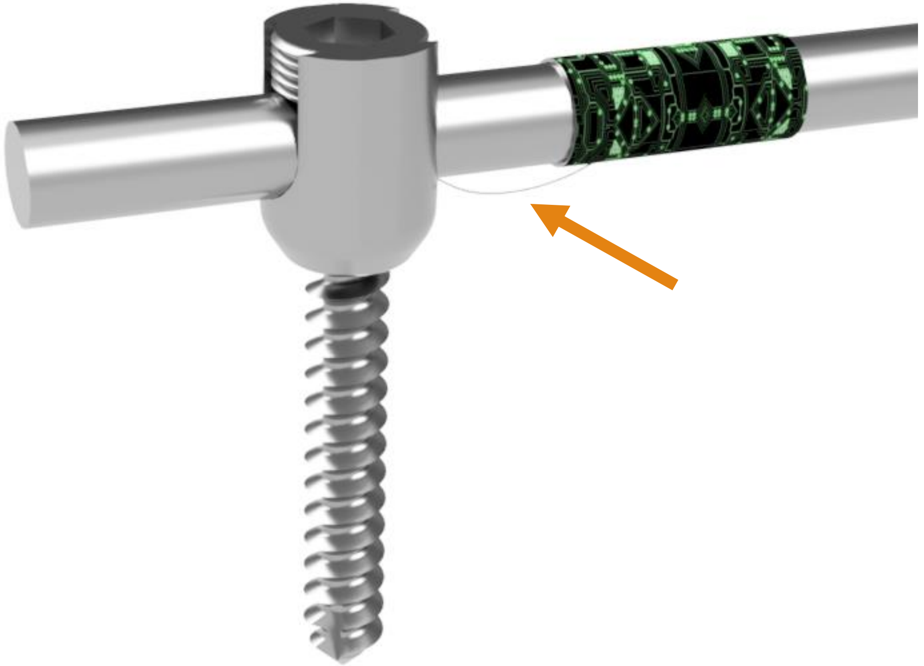
Overview

Four Main Categories of Design:

- Mechanical
- Power
    - Power transfer
- Circuit Logic
- Circuit Output

Design Alternatives: Mechanical

- Sleeve
- Tulip cap
- Sticker
- Rod alternatives



Pros:

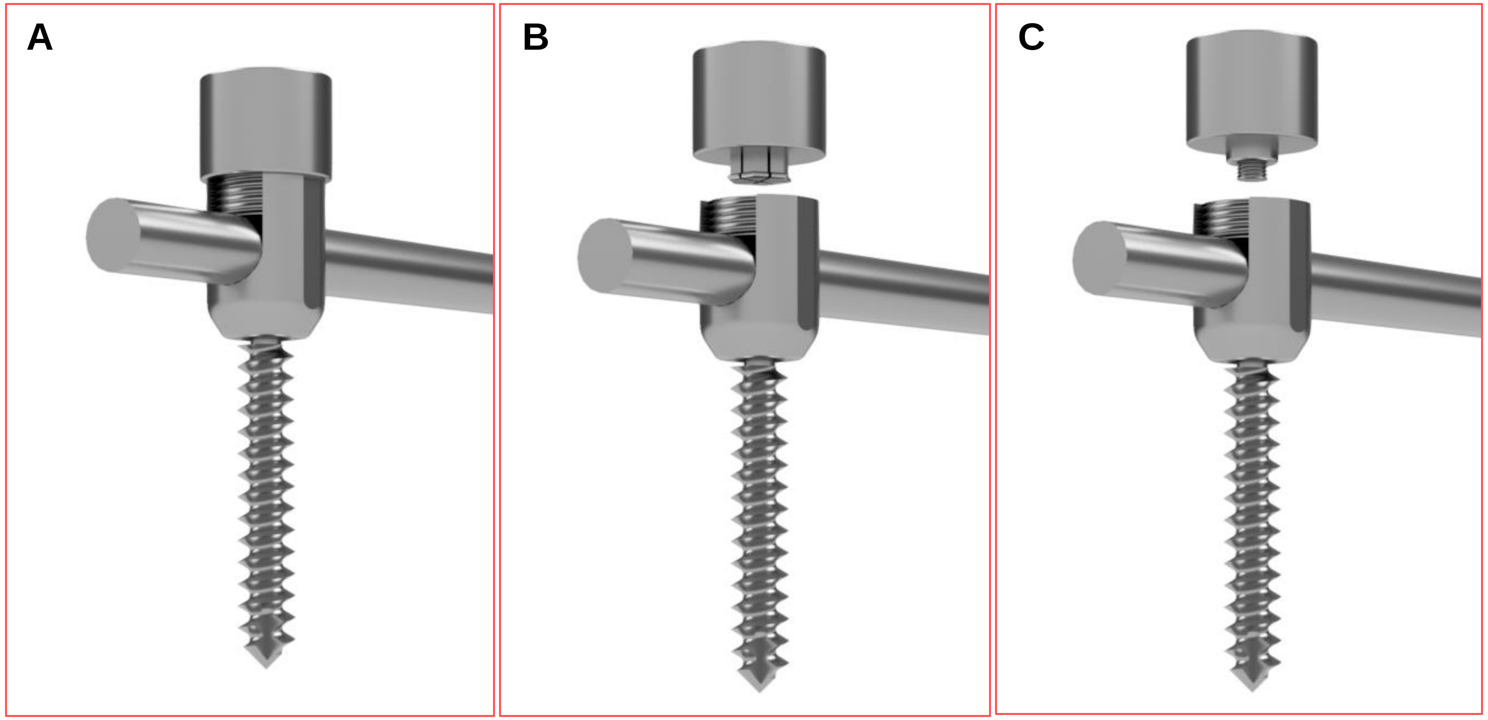
- Uniform resorption of a transient solution
- Adjustable positioning for non-transient solutions

Cons:

- Difficulty of fabrication
- Depending on position:
  - Strain on interface
  - Length of exposed wire /electrical connection
  - Minimum constraint on rod length

Design Alternatives: Mechanical

- Sleeve
- Tulip cap
- Sticker
- Rod alternatives



Pros:

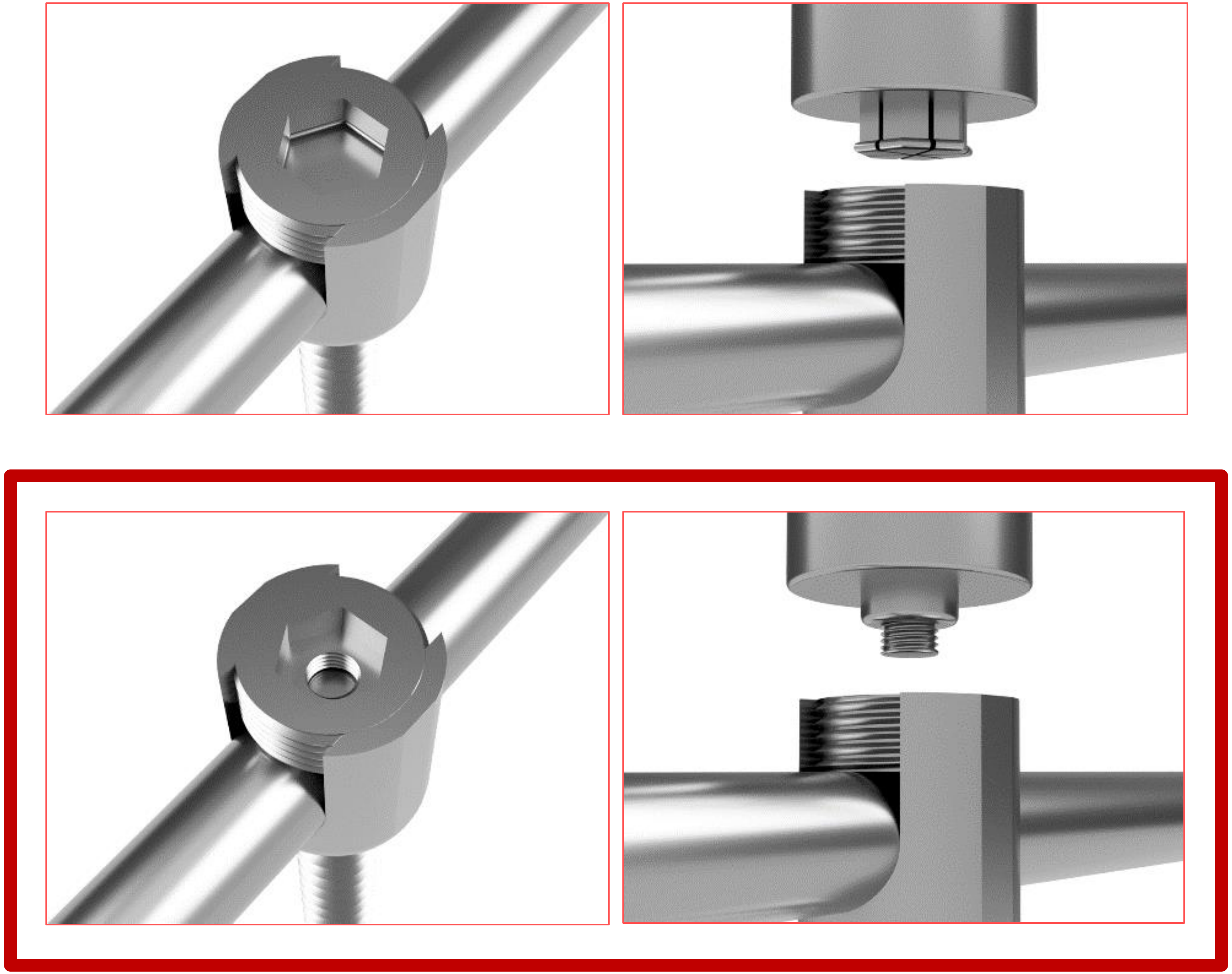
- Mechanically secure
- Modification to existing component
- Reasonable ease of fabrication

Cons:

- Engineering an electrical connection that does not inhibit polyaxial screw
- Risky for transient solutions

Design Alternatives: Mechanical

- Sleeve
- Tulip cap
- Sticker
- Rod alternatives

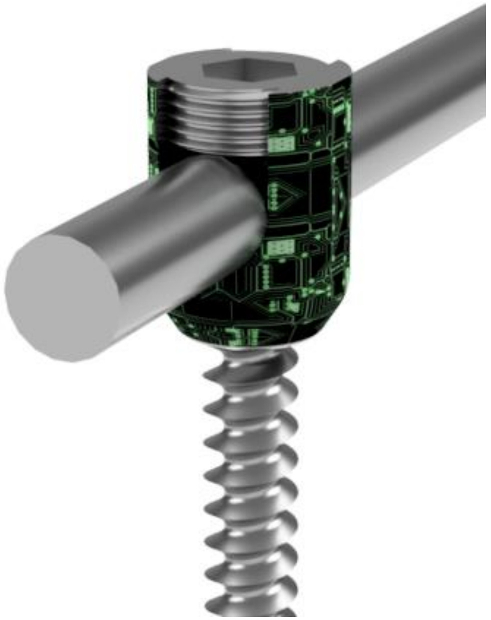


Design Alternatives: Mechanical

- Sleeve
- Tulip cap
- Sticker
- Rod alternatives

Pros:

- Ease of use for surgeon
- Reproducible
- Potential for both transient and non-transient solutions



Cons:

- Difficulty of fabrication
- Additional variable in the biocompatible adhesive; must last indefinitely

Design Alternatives: Mechanical

- Sleeve
- Tulip cap
- Sticker
- Rod alternatives

Nonconductive Ceramics:

- Alumina
- Zirconia

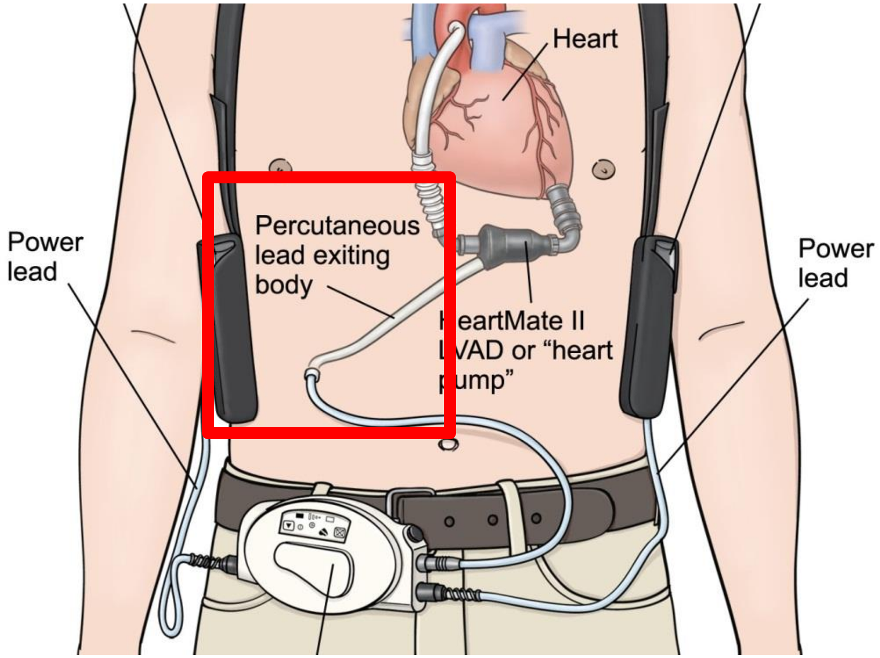
Polymer-Coating:

- Silicon
- Polyethylene

Properties of Nonconductive Ceramics						
	Femur	**Cervical**	**Lumbar**	**Ti-6Al-4V**	**Zirconia**	**Alumina**
Compressive Strength (Mpa)	167	10	5	1070	2000	4000
Tensile Strength (MPa)	121	3.1	3.7	960	820	69-665
Elastic Modulus (GPa)	17.2	0.23	0.16	110	220	380
Electrical Resistivity (Ω cm)				1.7×10^{-4}	$> 1 \times 10^{12}$	$> 1 \times 10^{14}$

Design Alternatives: Power

- Percutaneous wire
- Single-use battery
- Rechargeable battery
- Capacitor bank
- Constant wireless power transmission



Pros:

- Lossless power transmission

Cons:

- Risk of infection
- Patient discomfort
- Additional procedure required to remove wire

Design Alternatives: Power

- Percutaneous wire
- Single-use battery
- Rechargeable battery
- Capacitor bank
- Constant wireless power transmission

Single-use Battery

Pros:
- Solution currently employed by client
- No requirement for patient compliance

Cons:
- Size is the limiting factor for miniaturizing product
- Solutions cannot be made 100% transient

Rechargeable Battery

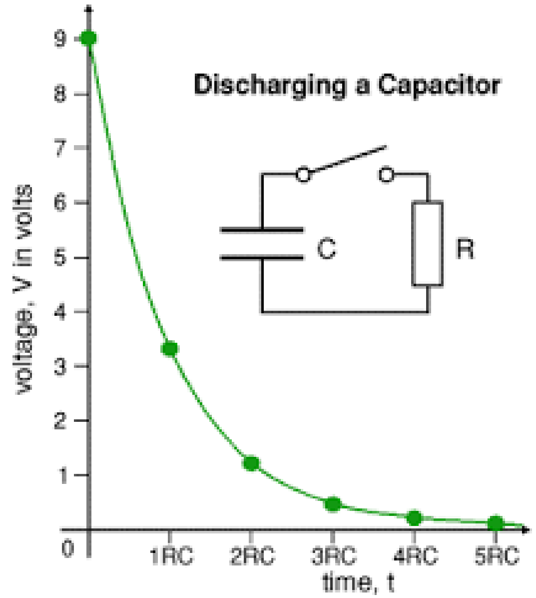
Pros:
- Less imposing size
- Can be utilized long after initial treatment period

Cons:
- Therapeutic efficacy reliant on repeated patient compliance
- Solutions cannot be made 100% transient

Design Alternatives: Power

- Percutaneous wire
- Single-use battery
- Rechargeable battery
- Capacitor bank
- Constant wireless power transmission

Rechargeable Capacitor Bank



Cons:
- Likely imposes on size constraints
- Exponential capacitive decay
- Therapeutic efficacy reliant on repeated patient compliance

Constant Wireless Power Transmission

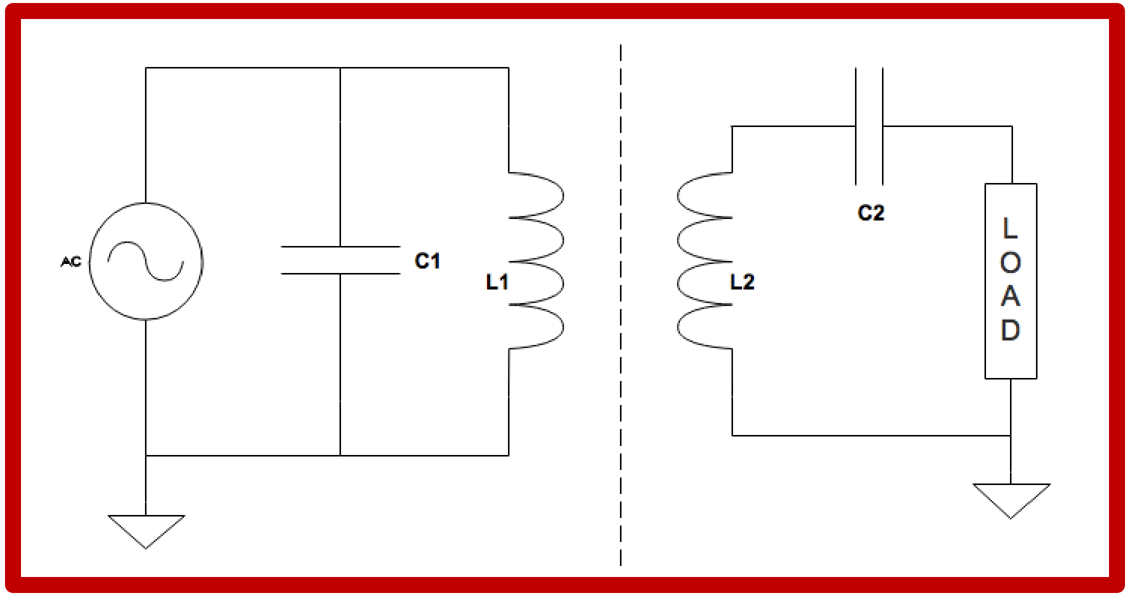
Pros:
- Enables further miniaturization
- Allows for 100% transient solution

Cons:
- Poor therapeutic efficacy
  - Sustained precise positioning
  - Patient compliance

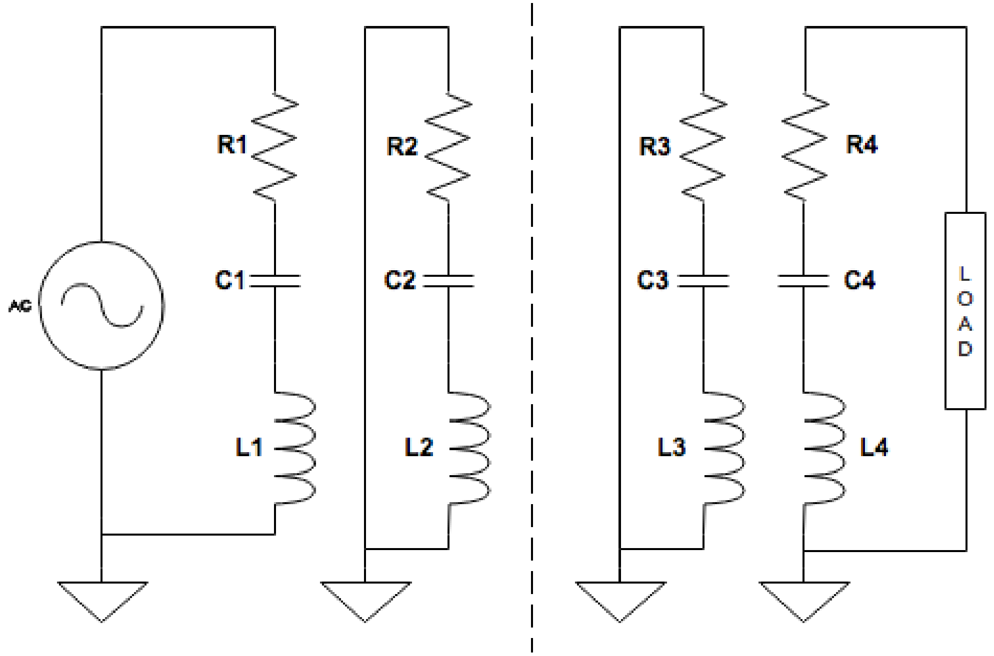
Design Alternatives: Power Transfer

- Simple induction
- High frequency resonance induction

Simple induction

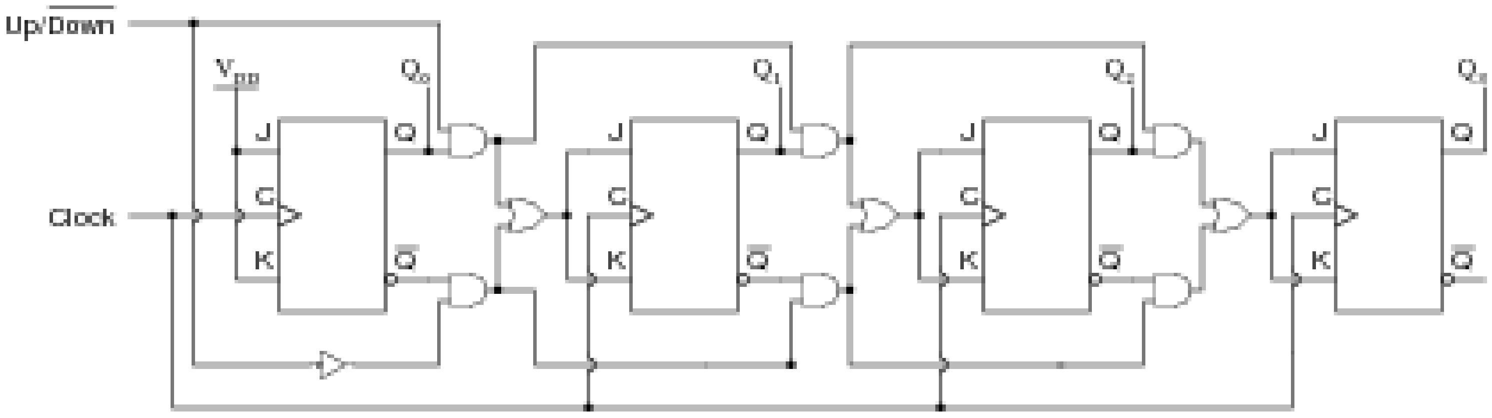


High frequency resonance induction



Design Alternatives: Circuit Logic

- Binary counter
- Microcontroller



Pros:

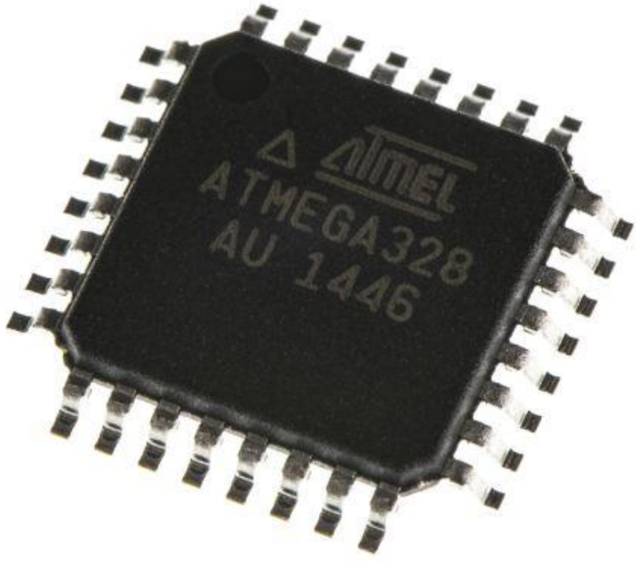
- Prior use in client's studies
- Potential for transient solution

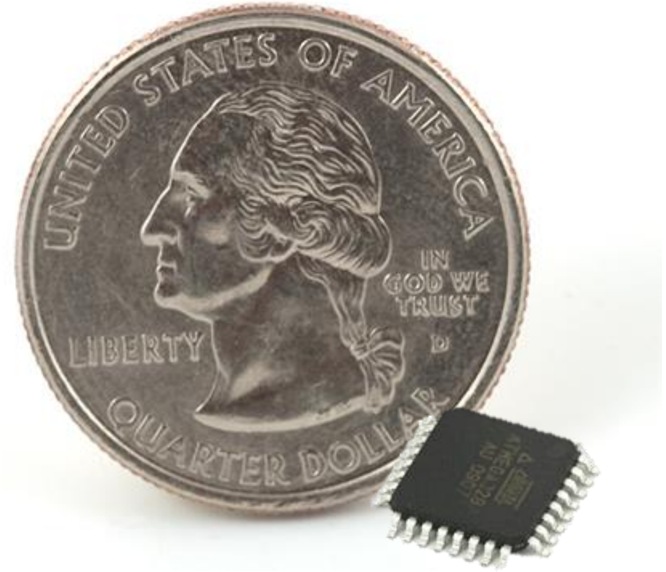
Cons:

- Size
- No two-way communication
- Accuracy of current amplitude adjustment

Design Alternatives: Circuit Logic

- Binary counter
- Microcontroller



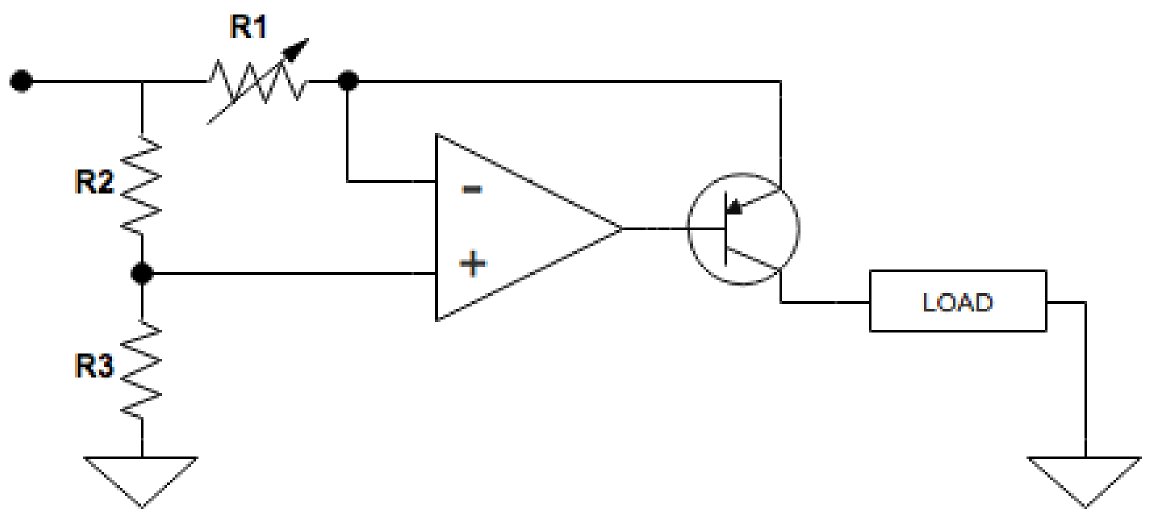


Pros:
- Enhanced addressability
- Programmable in Arduino IDE
- Capable of meeting size constraints

Cons:
- Solution cannot be 100% transient

Design Alternatives: Current Output

- Simple transistor
- Chip-controlled

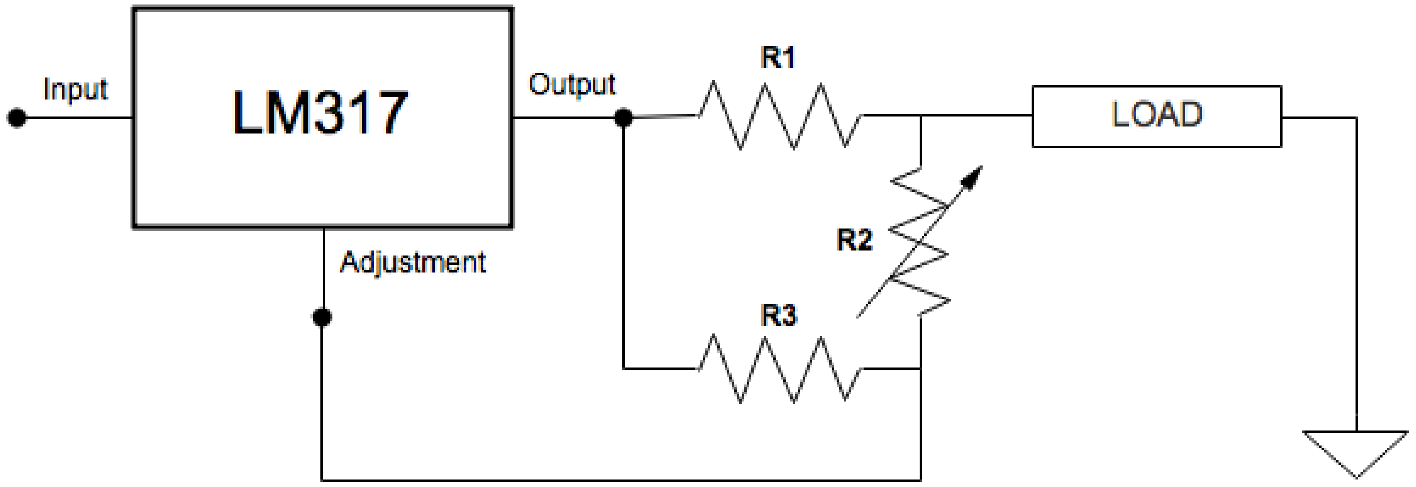


Pros:
- Simple components required; low quantity
- Potential for 100% transient solution

Cons:
- Less stable output
- No built in safety for temperature or current surges

Design Alternatives: Current Output

- Simple transistor
- Chip-controlled



Pros:
- Built-in over-temp & over-current protection
- Stable output despite variable input
- Enhanced addressability

Cons:
- Larger circuit
- Reliance on LM317

Design Selection: Possibilities

The ten design solutions to be analyzed and considered in depth

Solution	Circuitry Attachment	Logic	Power	Rod	Stimulating Circuit	Transient
1	Tulip cap	Microcontroller	Rechargeable	Polymer-coated	Simple transistor	No
2	Tulip cap	Microcontroller	Single-use	Polymer-coated	Simple transistor	No
3	Tulip sticker	Microcontroller	Rechargeable	Polymer-coated	Simple transistor	No
4	Tulip sticker	Microcontroller	Single-use	Polymer-coated	Simple transistor	No
5	Sleeve	Microcontroller	Rechargeable	Nonconductive ceramic	Simple transistor	No
6	Sleeve	Microcontroller	Single-use	Nonconductive ceramic	Simple transistor	No
7	Sleeve	Binary counter	CWPT	Nonconductive ceramic	Simple transistor	Yes
8	Tulip sticker	Binary counter	CWPT	Polymer-coated	Simple transistor	Yes
9	Tulip cap	Microcontroller	Rechargeable	Polymer-coated	Chip-controlled	No
10	Tulip cap	Microcontroller	Single-use	Polymer-coated	Chip-controlled	No

Design Selection: Criteria

Design specifications used to analyze the solutions

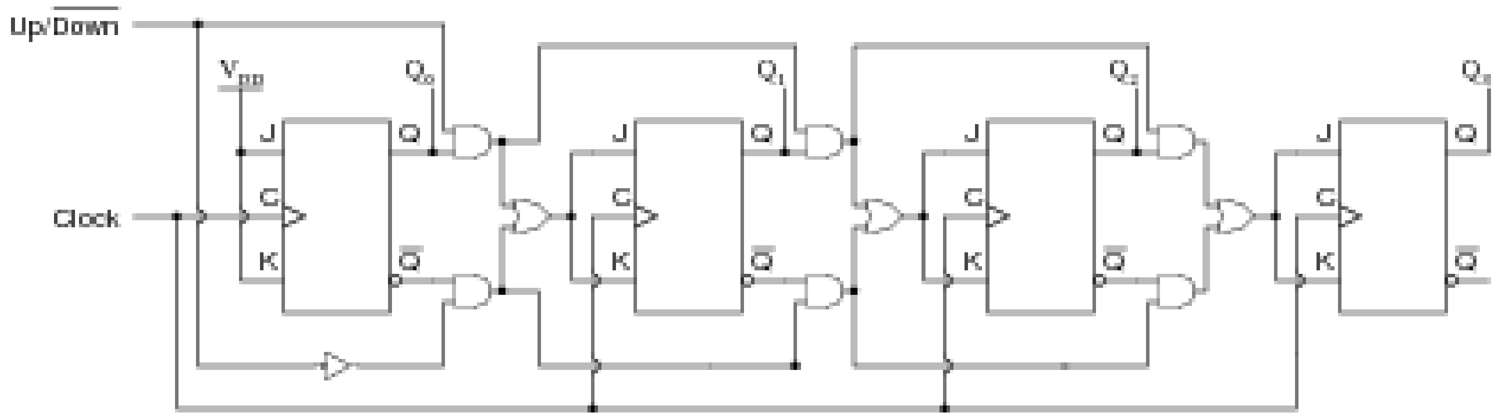
Criteria:

- Addressability
- Attachment
- Cost of R&D
- Current Output
- Ease of Use for Surgeon
- Lifetime
- Patient Compliance
- Reproducibility
- Safety
- Size

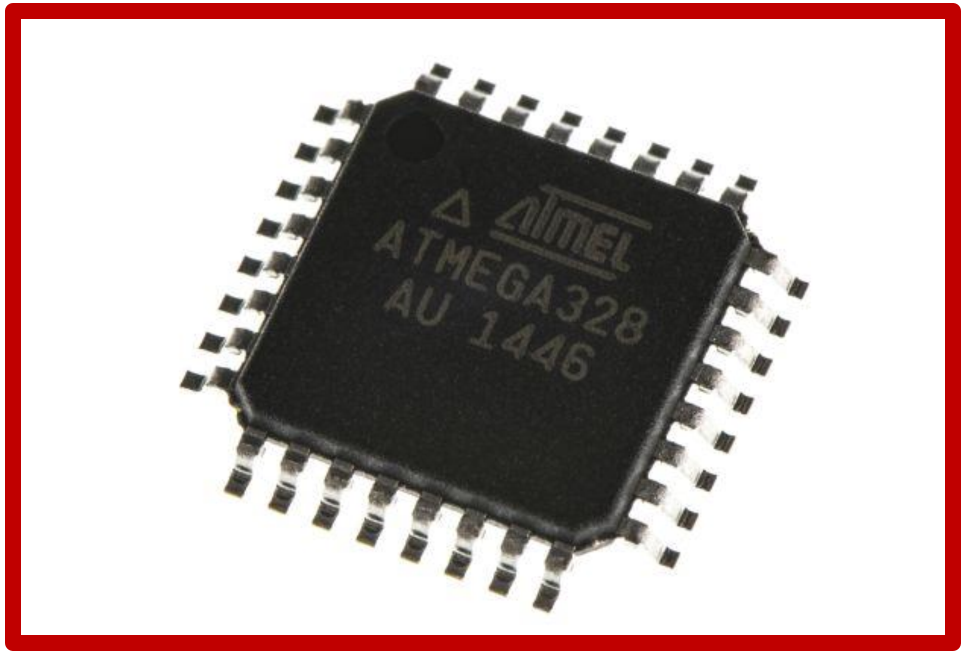
Design Selection: Criteria

- **Addressability**
- Attachment
- Cost of R&D
- Current output
- Ease of use for surgeon
- Lifetime
- Patient compliance
- Reproducibility
- Safety
- Size

Addressability



VS.



Design Selection: Criteria

- Addressability
- **Attachment**
- Cost of R&D
- Current output
- Ease of use for surgeon
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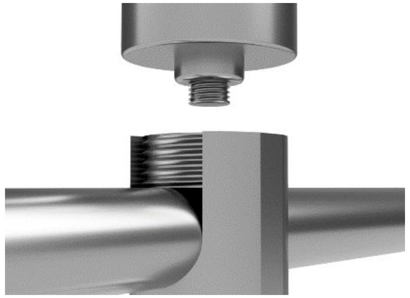
- Safety
- Size

Attachment

Mechanical Stability

1.



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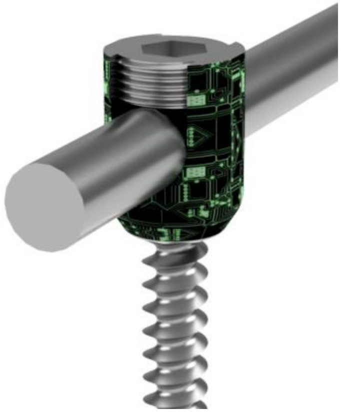
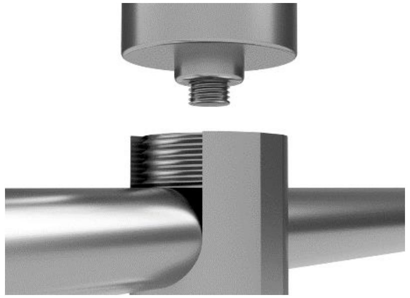
3.



Ease of Fabrication

1.



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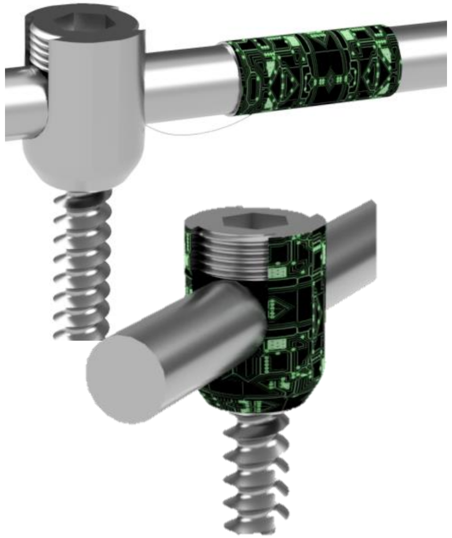

Design Selection: Criteria

- Addressability
- Attachment
- Cost of R&D
- Current output
- Ease of use for surgeon
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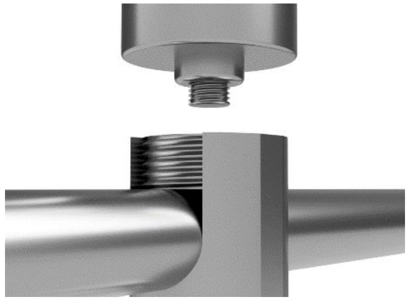
- Safety
- Size

Addressability

Overall

1.



2.

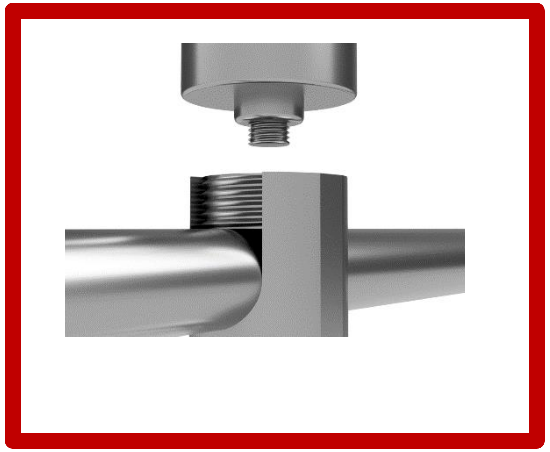
3.

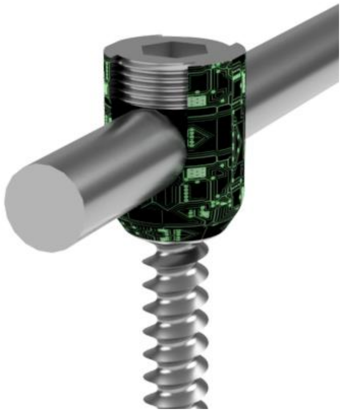
Design Selection: Criteria

- Addressability
- Attachment
- **Cost of R&D**
- Current output
- Ease of use for surgeon
- Lifetime
- Patient compliance
- Reproducibility
- Safety
- Size

Cost of R&D

Mechanical





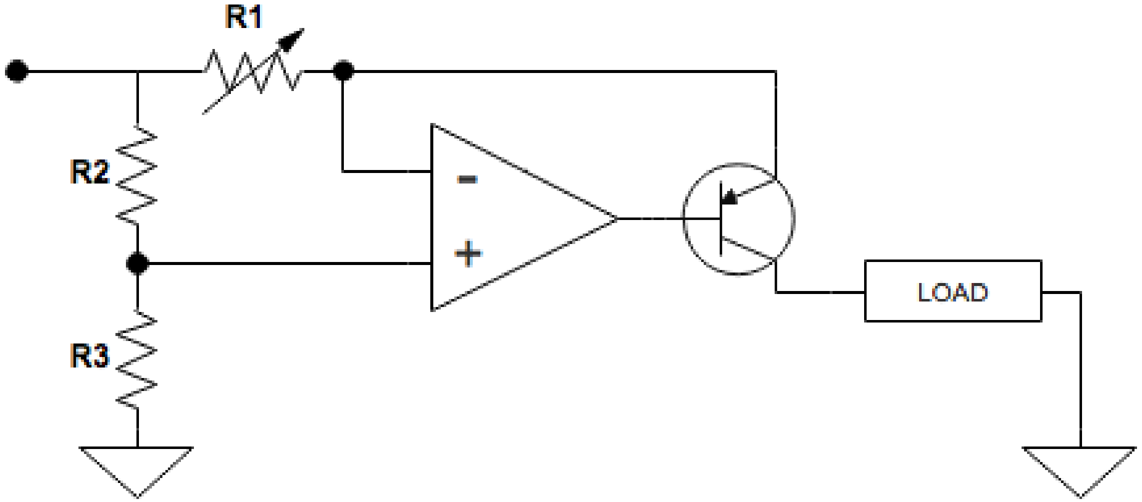
Power

1. Single-use battery
2. Rechargeable battery
3. Constant wireless power transmission

Design Selection: Criteria

- Addressability
- Attachment
- Cost of R&D
- **Current output**
- Ease of use for surgeon
- Lifetime
- Patient compliance
- Reproducibility
- Safety
- Size

Current Output



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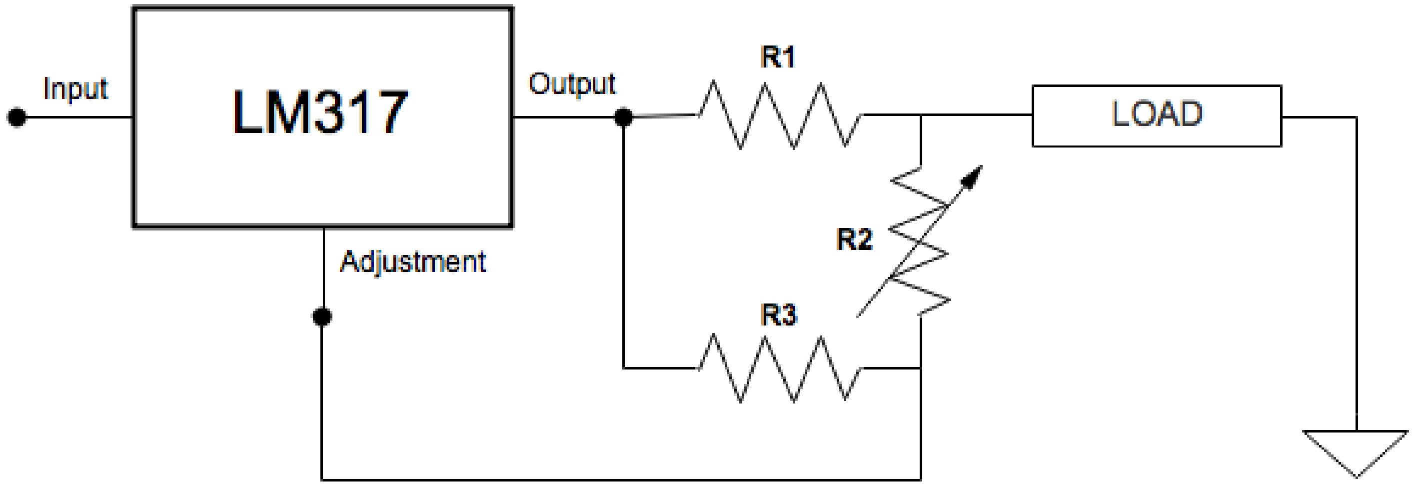
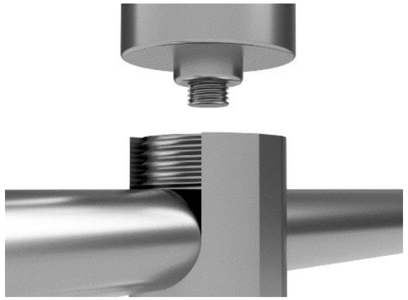


Design Selection: Criteria

- Addressability
- Attachment
- Cost of R&D
- Current output
- Ease of use for surgeon
- Lifetime
- Patient compliance
- Reproducibility
- Safety
- Size

Ease of Use for Surgeon

1.



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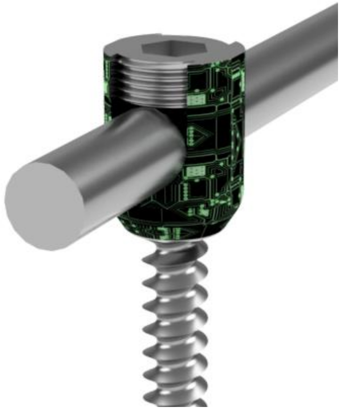

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Design Selection: Criteria

- Addressability
- Attachment
- Cost of R&D
- Current output
- Ease of use for surgeon
- Lifetime
- Patient compliance
- Reproducibility
- Safety
- Size

Lifetime

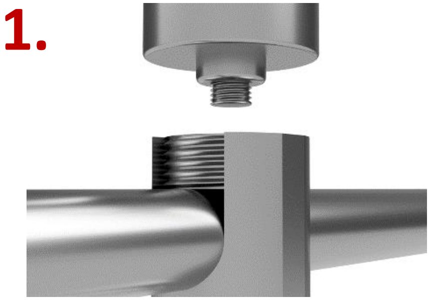
Material

1. Permanent
2. Transient

Power

1. Rechargeable battery
2. Single-use battery
3. Constant wireless power transmission

Attachment

1. 

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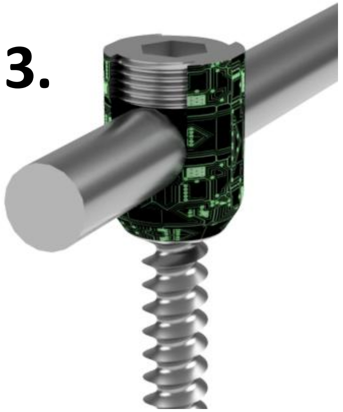
3. 

Design Selection: Criteria

- Addressability
- Attachment
- Cost of R&D
- Current output
- Ease of use for surgeon
- Lifetime
- **Patient compliance**
- Reproducibility
- Safety
- Size

Patient Compliance

Power

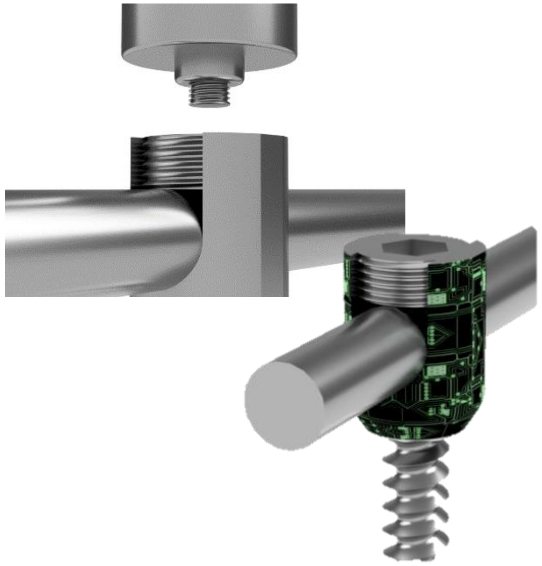
1. Single-use battery
2. Rechargeable battery
3. Constant wireless power transmission

Design Selection: Criteria

- Addressability
- Attachment
- Cost of R&D
- Current output
- Ease of use for surgeon
- Lifetime
- Patient compliance
- Reproducibility
- Safety
- Size

Reproducibility

1.



2.

Safety

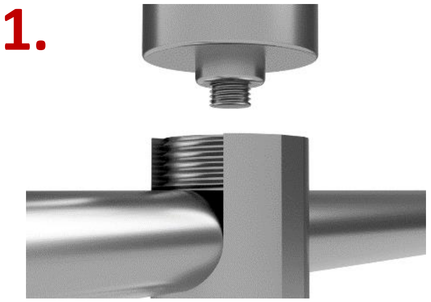
Design Selection: Criteria

- Addressability
- Attachment
- Cost of R&D
- Current output
- Ease of use for surgeon
- Lifetime
- Patient compliance
- Reproducibility
- Safety
- Size

Material

1. Transient
2. Permanent

Attachment

1. 

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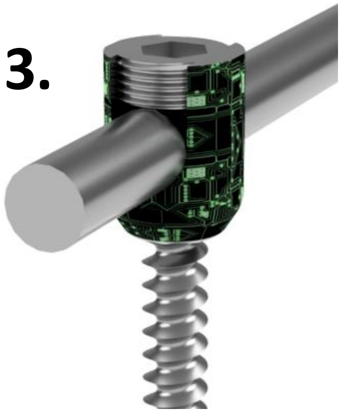
3. 

Design Selection: Criteria

- Addressability
- Attachment
- Cost of R&D
- Current output
- Ease of use for surgeon
- Lifetime
- Patient compliance
- Reproducibility
- Safety
- **Size**

Size

Circuit Logic

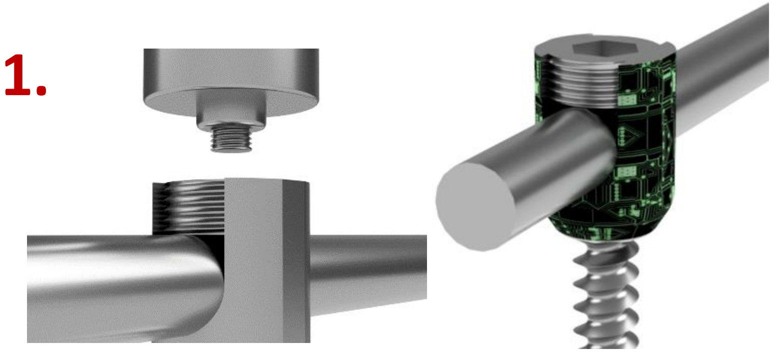
1. Microcontroller
2. Binary counter

Power

1. Constant wireless power transfer
2. Rechargeable battery
3. Single-use battery

Attachment

1.



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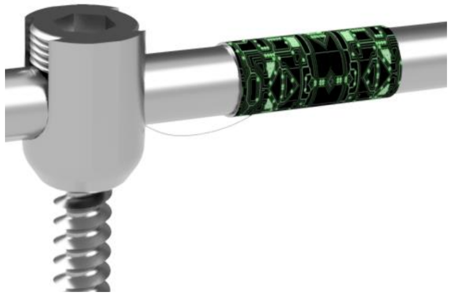


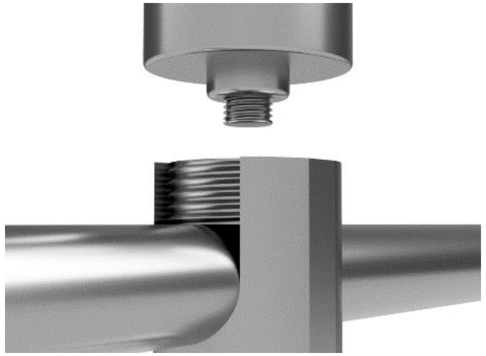
Pugh Chart											
	Importance	Solution 1	Solution 2	Solution 3	Solution 4	Solution 5	Solution 6	Solution 7	Solution 8	Solution 9	Solution 10
Current Output	10	9	9	9	9	9	9	9	9	10	10
Size	7	10	9	10	9	7	6	7	10	10	9
Lifetime	10	10	7	10	7	10	7	6	6	10	7
Addressability	8	10	10	10	10	10	10	6	6	10	10
Attachment	8	10	10	5	5	7	7	7	5	10	10
Cost of R&D	4	9	10	7	8	6	7	7	7	9	10
Safety	10	9	9	5	5	7	7	8	6	10	10
Patient Compliance	7	7	10	7	10	7	10	4	4	7	10
Ease of use for surgeon	9	10	10	10	10	6	6	6	10	10	10
Reproducibility	8	10	10	10	10	5	5	5	10	10	10
Sum		94	94	83	83	74	74	65	73	96	96
Weighted Total		765	753	677	665	612	600	533	594	785	773

Design Selection: Overview

Elaboration on what will be required for the chosen solution

Solution 9:

1. Tulip cap



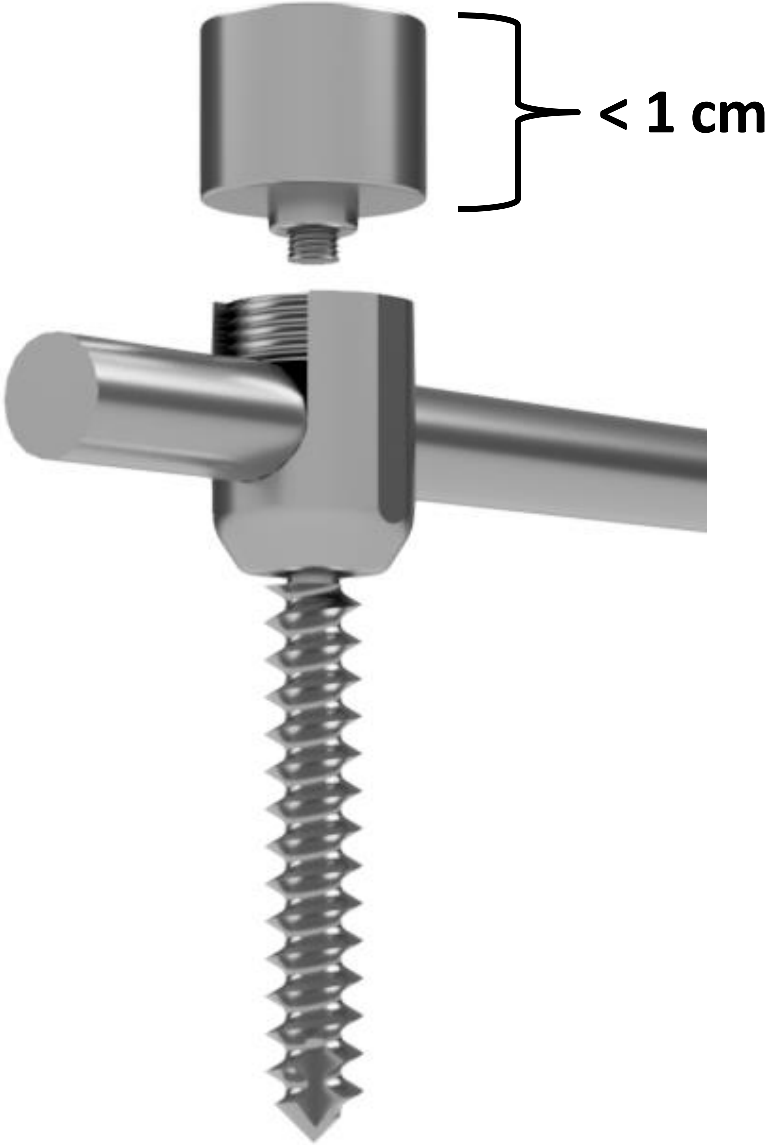
2. Polymer-coated rod
3. Microcontroller
4. Rechargeable battery
5. Chip-controlled stimulating circuit

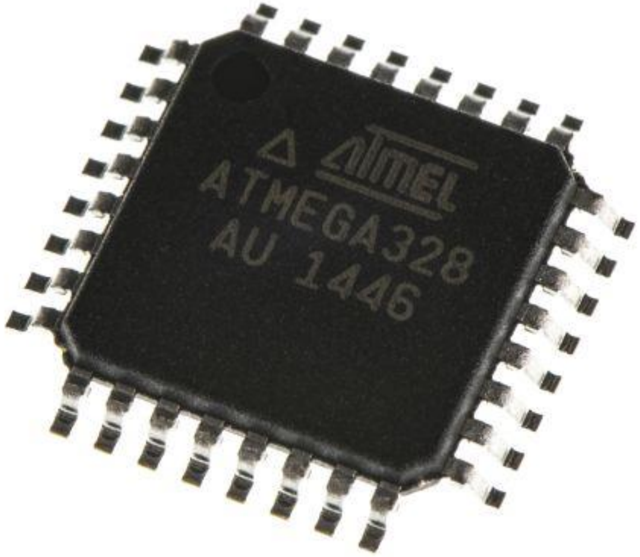
Design Selection: Overview

Elaboration on what will be required for the chosen solution

Design Selection: Overview

Elaboration on what will be required for the chosen solution





Proposed Budget

Expected cost of prototyping

Client Funded: <$500

Requested from Washington University:

Item	Quantity	Cost	Vendor
FTDI Basic Breakout	1	$14.95	Sparkfun
Magnet Wire Kit	1	$11.95	
Transistor NPN BC(337)	4	$2.00	
LM317 Voltage Regulator	2	$3.90	
Op-Amp LM358	1	$0.95	
ATtiny85	1	$2.84	
ATmega328P	1	$4.30	

Total: $40.89

Questions?

References

Special thanks to **Nathan Schmetter** for 3D models of mechanical solutions.

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