Tibial Stent Design Team Progress Report

Client: *Dr. Matthew Halanski*
Advisor: *Dr. Wan-Ju Li*

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Problem Statement

Tibia fractures are common in children, and these injuries are currently managed nonoperatively using casts; however, a surgically implanted device would provide more structural stability and aid the healing of the fracture. Adult patients with this injury typically have a rigid intramedullary device implanted into their tibia bone. Unfortunately, these implants cannot be used in pediatric patients due to the presence of growth plates at the implantation site. A previous design team produced a working device that can enter the medullary canal through a hole in the side of the bone and then expand outward to stabilize the fracture, held in place by static friction against the canal wall. This device is flexible enough to fit into the canal, yet rigid enough to maintain fracture reduction, can be secured in place with screws, and can be removed from the canal when desired; however, the device is not fully fixated against the walls of the bone canal, and the friction force of the device is not sufficient to prevent axial rotation within the canal. This rotation can lead to device failure resulting in unnecessary pain for the patient and extra surgery to correct the issue.

The goal of this semester is to improve the existing device by improving its fixation and adding more radial force thereby advancing this project toward clinical use.

Last Week's Goals (14-7 days ago)

- Based on quote from Potomac Laser, decide whether having a more reliable version of the device fabricated by laser drilling and laser microwelding is feasible given the budget and other necessary expenses
    - if the cost is reasonable, create drawings in SolidWorks of the existing device that can be manipulated, modified, and eventually sent to Potomac Laser
        - discussed making the end and mid caps larger to potentially accommodate another bowed wire – still investigating this possiblity
- Attempt to place the existing device inside the Flexo SS and Flexo SSXC braided cylinders separately
    - test the fit of the existing device inside the 2 diameters (3/8" and 1/2") of Flexo braided sleeves ordered this week
- Begin osseointegration testing of Flexo SS and SSXC with osteoblasts
- All team members without ECB 2005 (Biomaterials Lab) access request and obtain access

This Week's Goals/Individual Goals (7-0 days ago)

- Conduct mechanical testing on the Flexo SS and Flexo SSXC
    - measure outward force provided by a change in length
    - measure tensile force required for pull-through
- Quantify how much radial force the device needs to deliver to constitute "stabilizing the fracture"
    - because we are using the braided mesh, we can quantify this as the pressure along the cylinder because the cylinder is continuous, not discrete like the wire design was

- **Complete brainstorming of new locking mechanisms and evaluate them in another design matrix to determine the final design for this project**
- All team members without ECB 2005 (Biomaterials Lab) access request and obtain access

This Week's Accomplishments

- Postponed mechanical testing of braid until completion of mathematical modeling
- Mathematical modeling – quantify radial force the device needs to deliver
    - Treat device in bone as a beam with unique mechanical properties because the bending mechanical properties of the device change when it is applying pressure to the wall of the canal
    - Difficult to mathematically relate the outward pressure delivered by the device to the reaction strains that actually cause the device to resist bending
    - Instead, use a three-point bending test to determine the apparent flexural modulus (Young's modulus for bending; designated "apparent" because it is the flexural modulus of the "beam" which represents the device when it is applying pressure to the canal)
- Brainstormed more locking mechanism ideas
    - not ready to evaluate yet; **one more week at maximum**

Project Difficulties

- struggling to relate pressure applied to bone canal with apparent flexural modulus of "beam" mathematically – the problem is very complex
    - potential solution: use apparent flexural modulus as design criteria

Next Week's Team Goals

- **Complete mathematical modeling of problem** to determine design constraint that must be met to consider final design a success – apparent flexural modulus?
    - complete equation sheet with pathway from flexural modulus to displacement equation – displacement will be the criteria for our design; from it we can compute the apparent flexural modulus for the device that will allow this displacement.
- **Finish designing the locking mechanism** for this device and evaluate alternatives in design matrix to determine final design
- All team members without ECB 2005 (Biomaterials Lab) access request and obtain access

Summary of Design Accomplishments

- The team is meeting weekly to accelerate the design process
- The team has met with previous semester design team to better understand where the project currently stands
- The team has completed the problem statement and the PDS
- The team has used a design matrix to select the design alternative for the final design that best addresses the needs for the project
- The team has completed the Midsemester Presentation and Midsemester Report
- The team has ordered TechFlex Flexo Braided Stainless Steel sleeves for preliminary testing
- The team met with Dr. Yen (Biomechanics) who consulted on this project previously to discuss options and methods for mechanically testing axial rotation of the device inside of the bone canal

Expenses

- TechFlex Flexo-Braided Stainless Steel from wirecare.com - $47.15

Schedule for Fall 2013

Task	*September*				*October*				*November*					*December*	
	6	13	20	27	4	11	18	25	1	8	15	22	29	6	13
Groundwork															
Set Meeting Time	X	X													
Brainstorming	X	X	X	X	X			X	X						
Biomaterials Lab Access															
Research															
Tibia Fractures	X	X	X	X											
Stent Protocol	X	X	X	X	X										
Fixation Methods	X	X	X	X	X	X									
Contextual Research	X	X	X	X	X	X									
Prototyping															
Order Materials						X	X	X	X						
Build Prototype									X						
Test Prototype								X	X						
Deliverables															
Progress Reports	X	X	X	X	X	X	X	X	X						
Notebooks	X	X	X	X	X	X	X	X	X						
PDS			X	X	X	X	X	X	X						
Midsemester Presentation				X	X										
Midsemester Report				X	X	X									
Final Poster															
Final Report															
Meetings															
Advisor Meeting	X	X	X	X	X	X	X	X	X						
Team Meeting	X	X	X	X	X	X	X	X	X						
Client Meeting				X											
Website															
Update	X	X	X	X	X	X	X	X	X						

Activities

Person(s)	Task	Time (hrs)	Weekly Total	Semester Total
Evan	*Team Role (Leader)*		15.0	92.5
	Weekly progress report	1.5		
	Developed next week's team goals	1.0		
	Other			
	Mathematical Modeling Research/Equation Manipulation	10.0		
	Team Meeting	2.5		
Karl	*Team Role (Communicator)*		4.5	61.0
	n/a			
	Other			
	SolidWorks Modeling	2.0		
	Team Meeting	2.5		
Tyler	*Team Role (BSAC)*		1.0	35.0
	n/a			
	Other			
	Team Meeting	1.0		
Sarah	*Team Role (BWIG)*		4.5	48.0
	Update Website	0.5		
	Other			
	Locking Mechanism Research	2.0		
	Team Meeting	2.0		
Lida	*Team Role (BPAG)*		2.0	30.5
	n/a			
	Other			
	Team Meeting	2.0		