Tibial Stent Design Team Progress Report

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

Team:

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Date: *November 1st, 2013 – November 8th, 2013*

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)

- 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 Goals/Individual Goals (7-0 days ago)

- **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

<u>This Week's Accomplishments</u>

- Completed equation sheet using Euler-Bernoulli beam theory to mathematically relate force and displacement to the flexural modulus for three-point bending analysis
  - no direct mathematical connection exists between internal pressure provided by device or force between mid and end cap and the apparent flexural modulus of the device in fractured bone – once we have selected a braid we can empirically generate a relationship between the flexural modulus and the force applied between the caps and use that to determine the force necessary to reach the goal flexural modulus
- The reported flexural modulus for bone is 10-20 GPa, so the target flexural modulus for our device within a fractured bone is 15 GPa (this is equivalent to about 2mm of displacement under a load of 1000N in a 3-point bend test)
- **Locking Mechanism**
  - Have developed idea of spring to provide force between mid and end caps
    - complex extraction procedure that relies on being able to hook the midcap in order to remove the device – not ideal
    - lack of patient specificity – small changes in bone canal radius can cause very large changes in the apparent flexural modulus – would like a more adjustable method
  - Currently investigating segmented car-jack idea
    - the original problem with the car-jack design was the rigidity of the threaded center piece needed to drive the mid cap toward the end cap
    - If we segment the center piece with torsional springs between each segment, then the center piece would be able to enter the bone canal, and the force that the center piece would apply to the caps would also hold the joints in tension and prevent buckling at the joints
    - Furthermore, if the mid cap is made longer and positioned near one of the joints, it could be used to bridge one of the joints to strengthen the device
- Consider using metal ribbons for the braid rather than bundled wires
  - Pros: stronger, forms a nearly continuous surface leaving very little room for bone in-growth, larger pull-through force so more force could be applied between the caps without worrying about inversion of the braid
  - Cons: decreases flexibility – we will have to carefully select the thickness of ribbon and the density of the braiding so that the device can still make the 45° angle for insertion

<u>Project Difficulties</u>

- none at this time

<u>Next Week's Team Goals</u>

- Finish specifications of segmented car-jack and complete design matrix to compare spring and segmented car-jack designs – have final locking mechanism design determined by Tuesday (11/12)
- Contact fabrication firm about fabricating the caps and segmented center piece (if chosen) or custom spring supplier (if spring design selected)
- Investigate manufacturing firms that can manufacture ribbon braid design
- Have caps and locking device designed and ordered by Friday (11/15)
- Have custom ribbon braid ordered (if possible) by Friday (11/15)

<u>Summary of Design Accomplishments</u>

- 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
- The team is having regular meetings more frequently to further accelerate the design process

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										X					
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	X					
Build Prototype									X	X					
Test Prototype								X	X	X					
Deliverables															
Progress Reports	X	X	X	X	X	X	X	X	X	X					
Notebooks	X	X	X	X	X	X	X	X	X	X					
PDS			X	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	X					
Team Meeting	X	X	X	X	X	X	X	X	X	X					
Client Meeting				X											
Website															
Update	X	X	X	X	X	X	X	X	X	X					

Activities

Person(s)	Task	Time (hrs)	Weekly Total	Semester Total
Evan	*Team Role (Leader)*		17.0	109.5
	Weekly progress report	1.5		
	Developed next week's team goals	1.0		
	Other			
	Post-Advisor Meeting Meeting	2.0		
	Generated Equation Sheet	3.0		
	Weekend Team Meeting	3.5		
	Welding Upgrade 1 Quiz	1.0		
	Weekly Team Meeting Tuesday	2.0		
	Wednesday Advisor Meeting	1.0		
	Segmented Car-Jack Brainstorming	2.0		
Karl	*Team Role (Communicator)*		8.5	69.5
	n/a			
	Other			
	Post-Advisor Meeting Meeting	1.0		
	Weekend Team Meeting	3.5		
	Welding Upgrade 1 Quiz	1.0		
	Weekly Team Meeting Tuesday	2.0		
	Wednesday Advisor Meeting	1.0		
Tyler	*Team Role (BSAC)*		11.0	46.0
	n/a			
	Other			
	Weekend Team Meeting	3.5		
	Mathematical Modeling Research	3.0		
	SolidWorks (caps)	2.5		
	Weekly Team Meeting	2.0		
	Welding Upgrade 1 Quiz	1.0		
Sarah	*Team Role (BWIG)*		8.0	56.0
	Update Website	0.5		
	Other			
	Post-Advisor Meeting Meeting	2.0		
	Weekend Team Meeting	3.5		
	Weekly Team Meeting	2.0		
Lida	*Team Role (BPAG)*		9.0	39.5
	n/a			
	Other			
	Post-Advisor Meeting Meeting	1.0		
	Spring Modeling and Diagraming	3.5		
	Weekend Team Meeting	3.5		
	Weekly Team Meeting	1.0		