

Tibial Stent Design Team Progress Report

Client: Dr. Matthew Halanski

Advisor: Dr. Wan-Ju Li

Team: Evan Lange *elange2@wisc.edu (Team Leader)*
Karl Kabarowski *kabarowski@wisc.edu (Communicator)*
Tyler Max *tmax@wisc.edu (BSAC)*
Sarah Dicker *sdicker@wisc.edu (BWIG)*
Lida Acuna Huete *acunahuete@wisc.edu (BPAG)*

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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)

- **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

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

- 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)

This Week's Accomplishments

- Finished design & specifications of segmented car-jack mechanism
 - design matrix not yet completed; however, we are confident that the segmented carjack mechanism will integrate better into our existing design
 - **Pros of segmented carjack design:**
 - high amount of customizability to match patient specificity without physically altering components of the device to match the patient
 - simple insertion and extraction procedure
 - large amounts of force can be applied with this design, and the force can be carefully controlled by how much torsional force is applied to the centerpiece
 - with the addition of a locking nut, the device will definitely be able to hold the amount of force applied at surgery throughout the duration of implantation (no loss of force due to movement or over time)
 - **Cons of segmented carjack design:**
 - joints of centerpiece will likely be the failure-point of the device because they are so small – these joints are in tension
 - design can be further optimized in the future to maximize the ultimate strength of these joints
 - need to develop method to twist the centerpiece that can also be inserted into the hole in the side of the bone – future work
- Began investigation of fabrication firms that can fabricate the caps and segmented carjack centerpiece
- Pushed back ordering from Friday (11/15/13) to Monday (11/18/13) to allow time to incorporate Dr. Halanski's feedback
 - meeting on Friday (11/15/13)
- Determined that if no fabrication option is available, we could fabricate the ribbon braid by braiding metal strips around a rod of the desired diameter
 - this allows us to customize the braid without having to order multiple versions
 - may be fabricated by professional firm in the future
 - if this does not work, we can fall back on the TechFlex Flexo braid that we ordered previously

Project Difficulties

- none at this time

Next Week's Team Goals

- Order all components of device by Monday (11/18/13) after integrating Dr. Halanski's feedback
 - number of copies of device components to be determined – allow for assembly error
- Order metal ribbon material to attempt to make a biaxial braided sleeve
 - thickness and width to be determined
- Draw up a protocol for testing the device
 - flowchart diagram for testing this device
 - what equipment is necessary? how will the device be inserted? etc.
- BME 300 team members attend Welding 1 seminar and gain experience welding small objects
- We do not anticipate receiving parts from the fabrication firm until next week; however, if parts do arrive, we will *immediately* proceed to device assembly to begin testing as soon as possible

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
- 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	X				
Build Prototype									X	X	X				
Test Prototype								X	X	X	X				
Deliverables															
Progress Reports	X	X	X	X	X	X	X	X	X	X	X				
Notebooks	X	X	X	X	X	X	X	X	X	X	X				
PDS			X	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	X				
Team Meeting	X	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	X				

Activities

Person(s)	Task	Time (hrs)	Weekly Total	Semester Total
Evan	<i>Team Role (Leader)</i>		9.0	118.5
	Weekly progress report	1.5		
	Developed next week's team goals	1.0		
	<i>Other</i>			
	Design Brainstorming	2.0		
	Weekly Team Meeting	2.0		
	Team Meeting (Wednesday)	2.5		
Karl	<i>Team Role (Communicator)</i>		7.0	76.5
	Contact Client for meeting	0.5		
	Contact Advisor for meeting reschedule	0.5		
	<i>Other</i>			
	Post-Advisor Meeting Meeting	0.5		
	Design Brainstorming	1.0		
	Weekly Team Meeting	2.0		
	Team Meeting (Wednesday)	2.5		
Tyler	<i>Team Role (BSAC)</i>			46.0
	n/a			
	<i>Other</i>			
	n/a			
Sarah	<i>Team Role (BWIG)</i>		5.5	61.5
	Update Website	0.5		
	<i>Other</i>			
	Post-Advisor Meeting Meeting	0.5		
	Weekly Team Meeting	2.0		
	Team Meeting (Wednesday)	2.5		
Lida	<i>Team Role (BPAG)</i>		6.5	46.0
	n/a			
	<i>Other</i>			
	Research/Brainstorming	2.0		
	Weekly Team Meeting	2.0		
	Team Meeting (Wednesday)	2.5		