P15001: Soft Ankle-Foot Orthotic

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P15001 Team

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Agenda

- Project Background
- Problem statement
- Use scenarios
- Customer Requirements
- Engineering Requirements
- Risks
- Project plan

Project Background: Current Technology

- Foot drop is a neurological disorder which impairs the ability of an individual to dorsiflex the foot (i.e., point the toe upward)
- Patients who experience Foot Drop utilize an assistive device known as an ankle-foot orthotic (AFO).
- Current AFO's are bulky, rigid, and disrupt the user's natural gait by providing assistance at all times, regardless of need.

[1]

Project Background: McKibben Muscle

- A McKibben Muscle is an artificial system that used substances like pressurized air to simulate human muscle movement
- Benefits:
  - Low cost system
  - Easily accessible and easy to make
- Costs:
  - Goes through pressurized air quickly and need a large supply
  - Non-linear and therefore difficult to model

[2]

Project Background: Stakeholders

- Users:
  - Users of AFOs
  - Patients' doctors
  - Therapists, caretakers

- Investors:
  - The customer: Dr. Elizabeth DeBartolo
  - Future investors in the final product

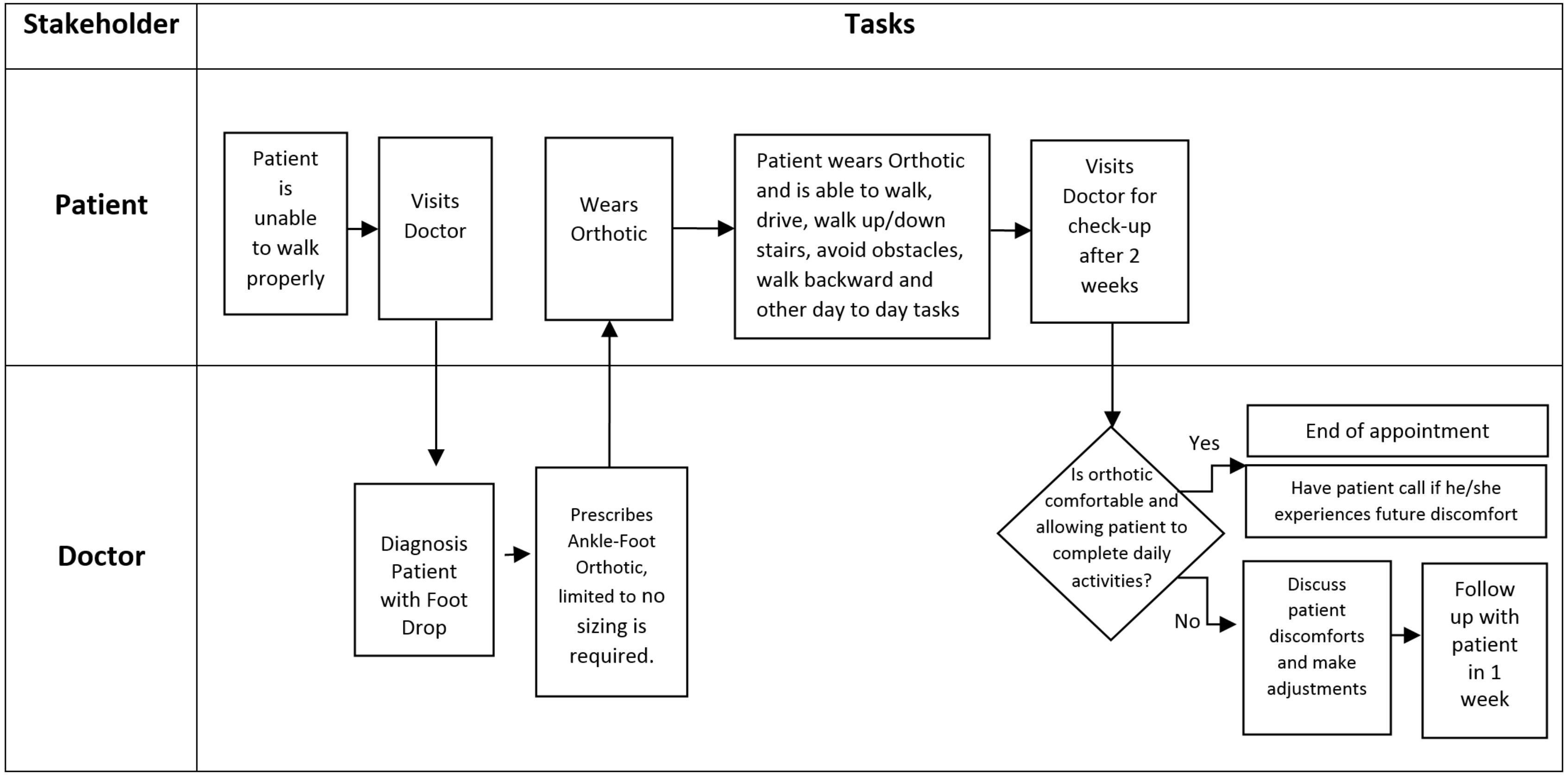
- Designers:
  - The members of this team
  - RIT Senior Design Program

Project Statement

The specific goal of our team is to incorporate previous work done, including McKibben muscles and the terrain sensing system, into an untethered AFO. It also should have an aesthetically pleasing flexible exoskeleton made from allergy conscious materials which comfortably fits into a user's existing footwear.

The exoskeleton needs to be integrated with the actuation device, sensing system, and microcontroller. The AFO must also must be capable of applying torque to and rotating the user's foot and should be designed to endure an entire day use untethered. The sensors and microcontroller system should incorporate the existing terrain sensing system as well as implementing more suitable heel strike sensing. The resulting design and prototype must follow the safety standards set forth by the Institutional Review Board as well as the ASME Boiler and Pressure Vessel Code.

Use Scenarios



Customer Requirements

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Category	Customer Rqmt. #	Importance	Description	Comments/Status
Safe	S1	9	safe for daily operation	
	S2	9	energy stored safely	
Functional	FT1	9	hold foot up when stepping forward	
	FT2	3	range of motion to allow full dorsiflexion and plantar flexion	
	FT3	3	operate smoothly/simulate normal muscle behavior	
	FT4	9	allow for extended use without straining leg from weight	
	FT5	1	Low battery alert	
Portable	P1	3	last for a full day without recharging/refueling	
	P2	3	stay secure throughout the day	
Confortable	CF1	9	Tolerable to wear for full day use	
	CF2	9	Not constrict blood flow	
	CF3	3	allow wide size range of users	
	CF4	1	allow normal cooling of leg	
	CF5	9	allow bending of knee	
	CF6	1	aesthetically pleasing	
	CF7	3	low noise	
Durable	D1	3	reliable for day to day usage	
	D2	1	usable in rain/shower	
Sense Terrain	ST1	9	allow natural movement up and down stairs and ramps	
	ST2	9	adapt to different terrains	
	ST3	3	fast system response between sensing and doing	
	ST4	3	correctly interprets sensor information	
	ST5	9	support foot drop over obstacles	
Convenient	C1	9	fit into normal shoe size	
	C2	1	reduce time and cost of custom fitting process	
	C3	3	easy to take off and put on	
	C4	1	easy patient interface with sensing system	

Importance: Sample scale (9=must have, 3=nice to have, 1=preference only)

Engineering Requirements

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rqmt. #	Importance	Source	Function	Engr. Requirement (metric)	Unit of Measure	Ideal Value	Comments/Status	Test (how are you going to verify satisfaction)
ER1	9	S1,CF1,CF2	Mechanical	Pressure to leg of AFO	mmHg	20		pressure sensor
ER2	3	D1		Sheer stress on hard plastics	MPa	800		ABS plastic test
ER3	3	CF1		Elasticity of material used for AFO base	GPa	2		ABS plastic test
ER4	2	S1,CF4		Average added heat from use	Degrees F	2		thermometer
ER5	9	FT1,FT3,ST5		Torque to lift foot by Mckibben air muscle	N-m	4		force gage
ER6	3	FT2,FT3		Dorsiflexion mobility with Mckibben air muscle	degrees	90		protractor
ER7	3	P1		Average time to pressurized air refill	hours	3		timer
ER8	9	S2,D2	Electrical	Battery in water repellant case	IP Code	54	5-solid object, 4-water	Ingress protection code (IP)
ER9	9	S1		Immediate Power Used	mW	2.5		multimeter
ER10	3	ST3		Response time of Terrain Sensor	ms	500		timer in microcontroller
ER11	3	P1		Total Power over Day Use	W	2		batteries used
ER12	9	S1,S2,D2		Sensors/controls water repellant	IP Code	54	5-solid object, 4-water	Ingress protection code (IP)
ER13	9	ST1,ST2,ST4		Error between Sensor data and physical distance	cm	7		ruler
ER14	9	FT4	Wearability	Physical size of AFO (dimmensions)	cm	20x30x30		ruler
ER15	3	C3		Average Time to put on AFO	min	5		timer
ER16	9	FT4		Weight of AFO	lbs	10	including compressed	scale
ER17	3	CF3,C2		Adjustable,trimmable,stretchable	yes/no	yes		survey
ER18	9	CF1,CF5		Difference in knee flex	degrees	0		protractor
ER19	1	CF1,CF6		Aesthetically pleasing	yes/no	yes		survey
ER20	9	CF1,CF7		Total running noise	dB	<60		db sensor
ER21	9	C1		Added foot width	cm	1		measure
ER22	1	FT5		Audible Low Battery Alert	dB	70		db sensor
ER23	1	C4		Easy to interface system	yes/no	yes		survey

Importance: Sample scale (9=must have, 3=nice to have, 1=preference only)

House of Quality

Row #	Max Relationship Value in Row	Relative Weight	Weight / Importance	Column #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
				Direction of Improvement: Minimize (▼), Maximize (▲), or Target (x)	▼	▼	▼	▼	▼	▲	▼	x	▼	x	▼	x	▼	▼	▼	▼	x	x	x	▼	x	▼	x		
				Quality Characteristics (a.k.a. "Functional Requirements" or "Hows") / Demanded Quality (a.k.a. "Customer Requirements" or "Whats")	Pressure to leg of AFO	Sheer stress on hard plastics	Elasticity of material used for AFO base	Average added heat from use	Torque to lift foot by Mckibben air muscle	Dorsiflexion mobility with Mckibben air muscle	Average time to pressurized air refill	Battery in water repellant case	Immediate Power Used	Response time of Terrain Sensor	Total Power over Day Use	Sensors/controls water repellant	Error between Sensor data and physical distance	Physical size of AFO (dimmensions)	Average Time to put on AFO	Weight of AFO	Adjustable,trimmable,stretchable	Difference in knee flex	Aesthetically pleasing	Total running noise	Added foot width	Audible Low Battery Alert	Easy to interface system		
1	3	7.2	9.0	safe for daily operation	O			O					O			▲													
2	9	7.2	9.0	energy stored safely								Θ				O													
3	9	7.2	9.0	hold foot up when stepping forward					Θ																				
4	3	2.4	3.0	range of motion to allow full dorsiflexion and plantar flexion						O																			
5	3	2.4	3.0	operate smoothly/simulate normal muscle behavior					O	O																			
6	9	7.2	9.0	allow for extended use without straining leg from weight														O		Θ									
7	9	0.8	1.0	Low battery alert																						Θ			
8	3	2.4	3.0	last for a full day without recharging/refueling							O				O														
9	3	2.4	3.0	Tolerable to wear for full day use	▲		O															▲	O	O					
10	9	7.2	9.0	Not constrict blood flow	Θ																								
11	3	2.4	3.0	allow wide size range of users																	O								
12	9	0.8	1.0	allow normal cooling of leg				Θ																					
13	9	7.2	9.0	allow bending of knee																		Θ							
14	9	0.8	1.0	aesthetically pleasing																			Θ						
15	3	2.4	3.0	low noise																				O					
16	3	2.4	3.0	reliable for day to day usage		O																							
17	3	7.2	9.0	allow natural movement up and down stairs and ramps													O												
18	9	7.2	9.0	adapt to different terrains													Θ												
19	3	2.4	3.0	fast system response between sensing and doing										O															
20	3	2.4	3.0	correctly interprets sensor information													O												
21	3	7.2	9.0	support foot drop over obstacles					O																				
22	3	7.2	9.0	fit into normal shoe size																					O				
23	9	0.8	1.0	reduce time and cost of custom fitting process																	Θ								
24	3	2.4	3.0	easy to take off and put on															O										
25	9	0.8	1.0	easy patient interface with sensing system																							Θ		
				Target or Limit Value																									
				Difficulty (0=Easy to Accomplish, 10=Extremely Difficult)																									
				Max Relationship Value in Column	9	3	3	9	9	3	3	9	3	3	3	3	9	3	3	9	9	9	9	3	3	9	9		
				Weight / Importance	88.8	7.2	7.2	28.8	93.6	14.4	7.2	64.8	21.6	7.2	7.2	28.8	93.6	21.6	7.2	64.8	14.4	67.2	14.4	14.4	21.6	7.2	7.2		
				Relative Weight	12.5	1.0	1.0	4.1	13.2	2.0	1.0	9.1	3.0	1.0	1.0	4.1	13.2	3.0	1.0	9.1	2.0	9.5	2.0	2.0	3.0	1.0	1.0		

Legend		
Θ	Strong Relationship	9
O	Moderate Relationship	3
▲	Weak Relationship	1
++	Strong Positive Correlation	
+	Positive Correlation	
−	Negative Correlation	
▼	Strong Negative Correlation	
▼	Objective Is To Minimize	
▲	Objective Is To Maximize	
X	Objective Is To Hit Target	

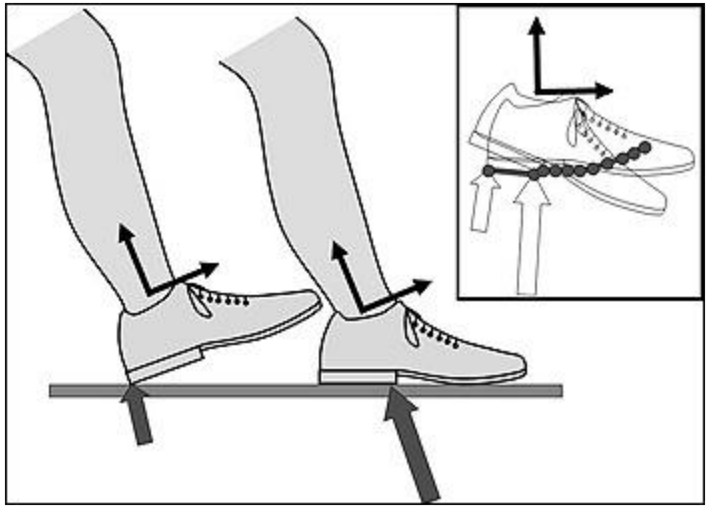
Constraints (1 of 2)

- The system must use untethered McKibben muscles as the means of foot actuation.

- The exoskeleton skeleton must be made out of a flexible, washable material. The material must also be hypoallergenic and non-abrasive without sharp protrusions.

- Use existing IR-based terrain sensing system. Heelstrike sensing may be adapted to a more suitable sensor.

- The AFO should also resist foot slap and keep toes from curling down.



[3]

Constraints (2 of 2)

- Device must accommodate a general range of population (5th percentile females to 95th percentile males)

- User must be able to wear his/her regular shoes while wearing device

- The device must follow safety standards as applicable including, but not limited to: Institutional Review Board (IRB) and ASME Boiler and Pressure Vessel Code.

Critical Design Challenges

- Creating a closed system with a day’s worth of pressurized air.
- Creating enough force to pull the foot up while not adding to the shoe size.
- Laying the muscles on a soft material.
- Keeping the weight low.
- Minimizing the gait and terrain monitoring system so that it can fit on the leg.
- More reliable source for heel strike sensing

Risks (1 of 2)

1. Team overdesigns the product creating an unfeasible design (e.g. addition of unnecessary functionality) and thus loses focus on the things that are most important
2. The AFO is too soft and thus not strong enough to provide the necessary force
3. The AFO is not able to accommodation of a wide range of foot sizes
4. Ability to provide necessary rigidness to the AFO without sacrificing comfort
5. The amount of air that the prototype will be able to hold will not be enough to last an entire day of use

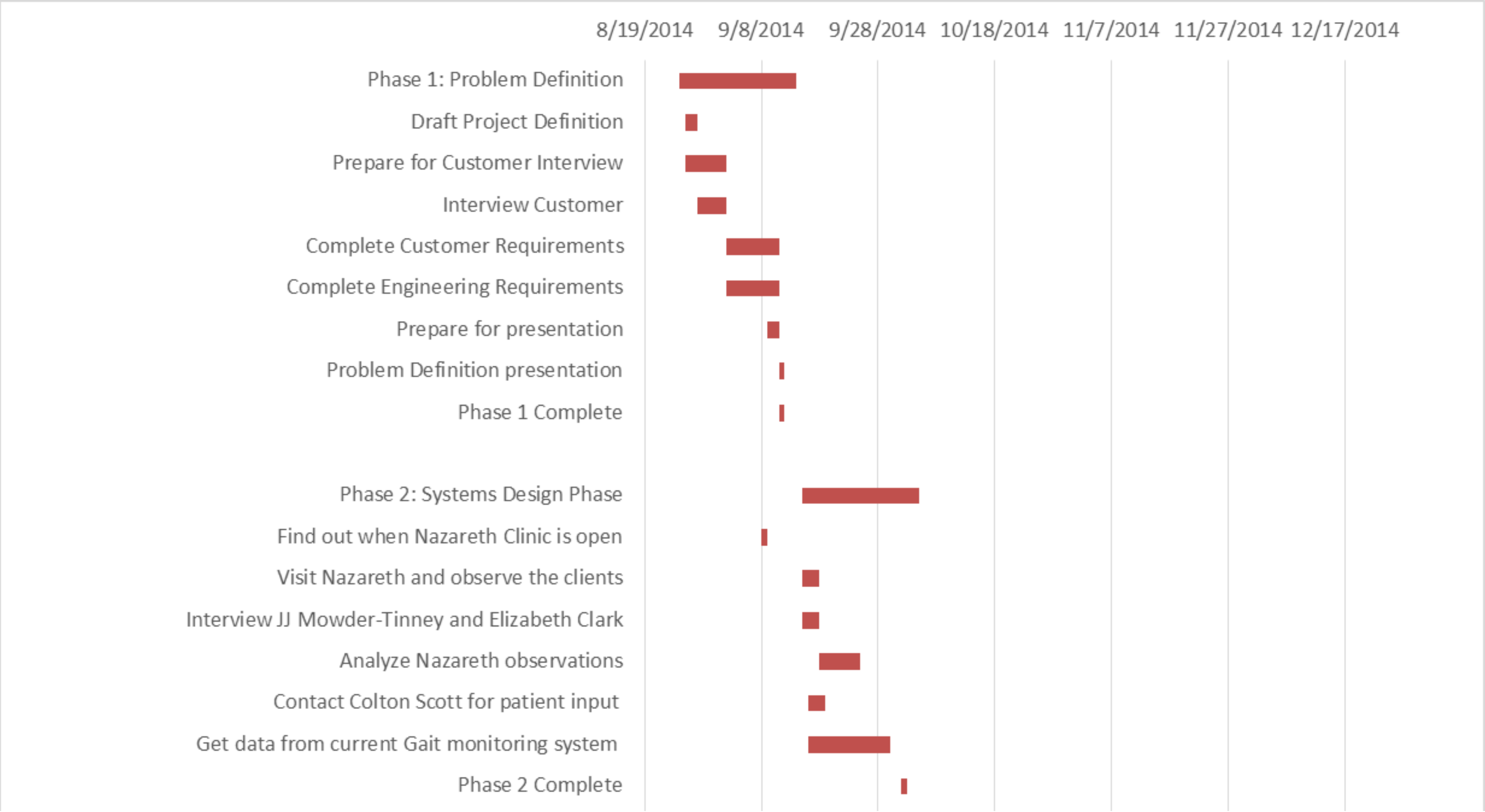
Risks (2 of 2)

6. Ability of air muscles to provide enough force to raise foot
7. Ability to find a light weight and low cost battery that can provide an entire day’s use
8. Reliability and safety of manual switch, especially for driving and stopping (and ease of use)
9. Terrain sensing for startup, stairs, ramps, and stopping
10. Finding a more reliable source for detecting heel strike.

Deliverables

- Prototype of untethered active system that has both terrain and gait sensing.
- Bill of Materials
- Detailed documentation of design
- Supporting test data and documentation
- User's guide for operation

Project plan



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[6] P14029 - Robotic Fish Powered by Hydraulic McKibben Muscles
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Questions?