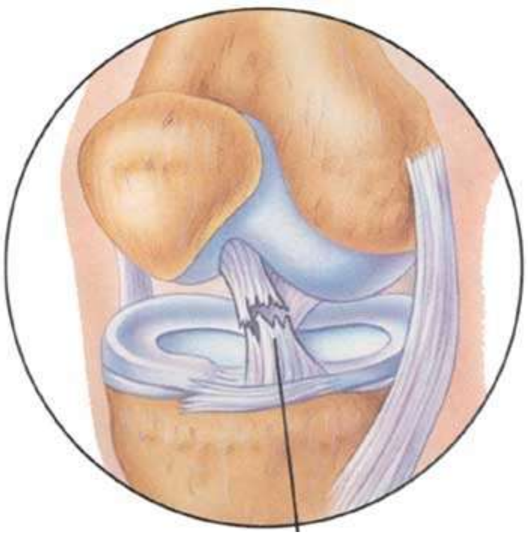
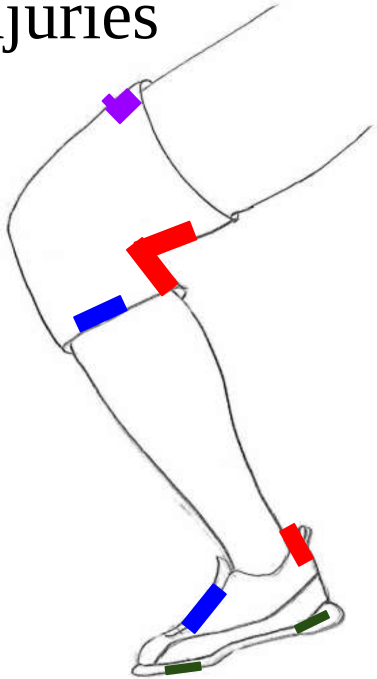
System Design of a Biofeedback Active Sensor System (BASS) to Mitigate the Probability of ACL Injuries



MARIBETH BURNS
ANDREW TESNOW
AMR ATTYAH
SAMUEL MILLER

SENIOR DESIGN SYST 495 - 001



The Epidemic -The Problem

- 300K Athletes tear their ACLs Every Year. CDC (2009)
- 13% of NCAA athletes tear their ACL Every Year. NCAA (2011)
- Women are 3 times more likely to tear their ACLs Beynnon (2008)
- The ACL keeps the Tibia from sliding forward past the Femur

Costs of A Tear - Money, Time, and Quality of Life

- ACL Reconstructive Surgery costs $60K to the medical health care system French-Owen (2013)

- It takes 6-9 months to recover from surgery. Briggs (2009)

- After Surgery, only 44% of athletes return to their pre-surgery level of performance Lee DY (2007)

Bojic (2015)

The “Knee Joint System

1. Femur
2. Patella
3. Tibia (shank)
4. Fibula (shank)

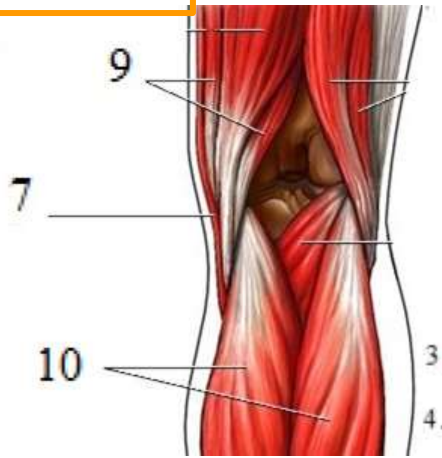
5. Quadriceps Tendon
6. Patellar Tendon
7. Hamstring Tendons

8. Quadriceps
9. Hamstring
10. Gastrocnemius

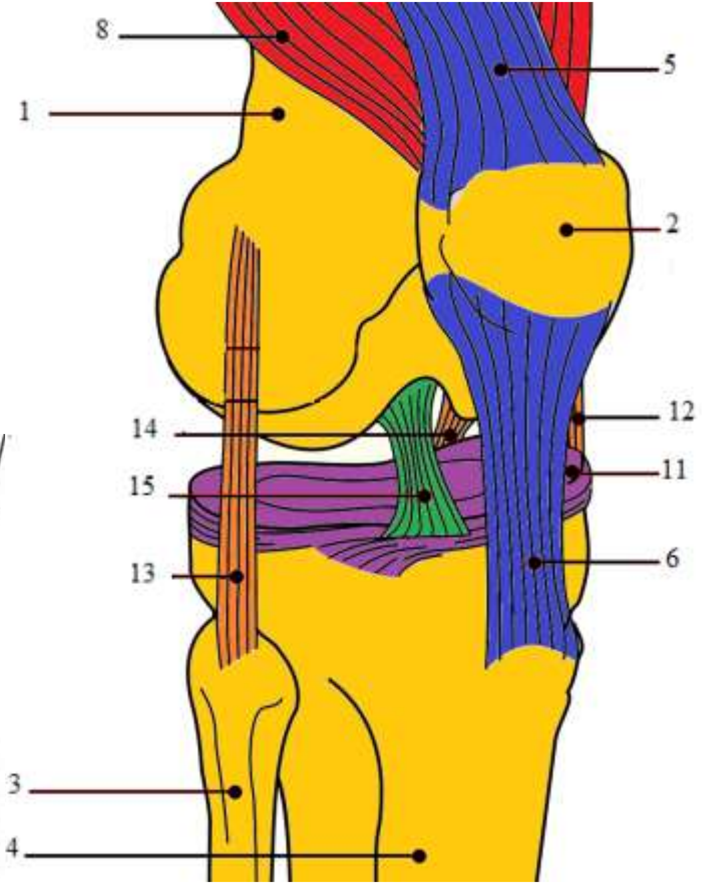
11. Meniscus

12. PCL
13. MCL
14. LCL

15. ACL



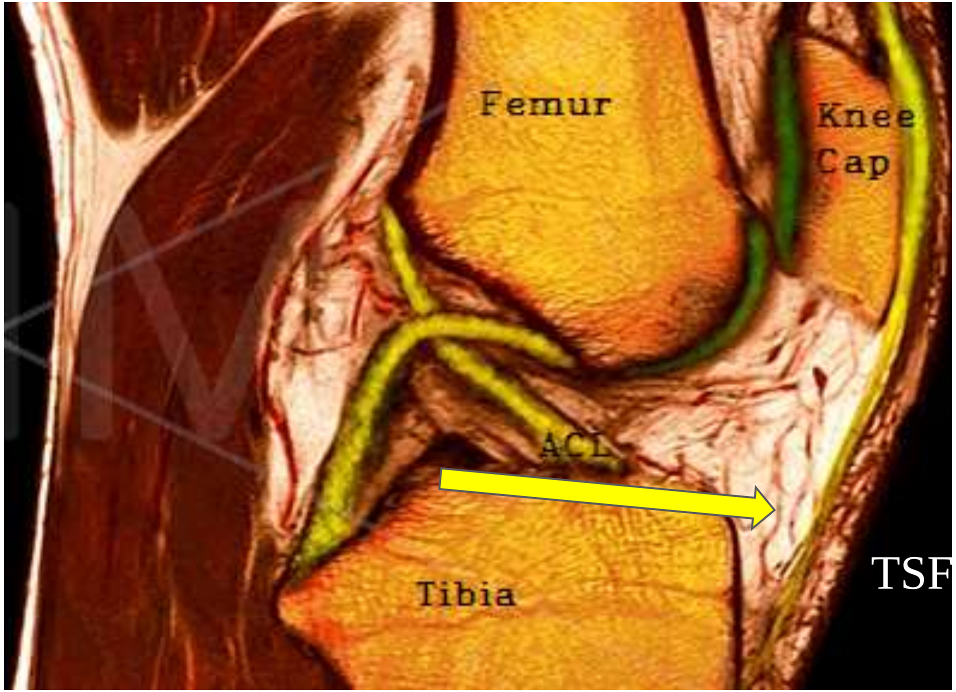
OhioDance (2012)



Wikipedia (2015)

Knee in the Sagittal Plane

Back



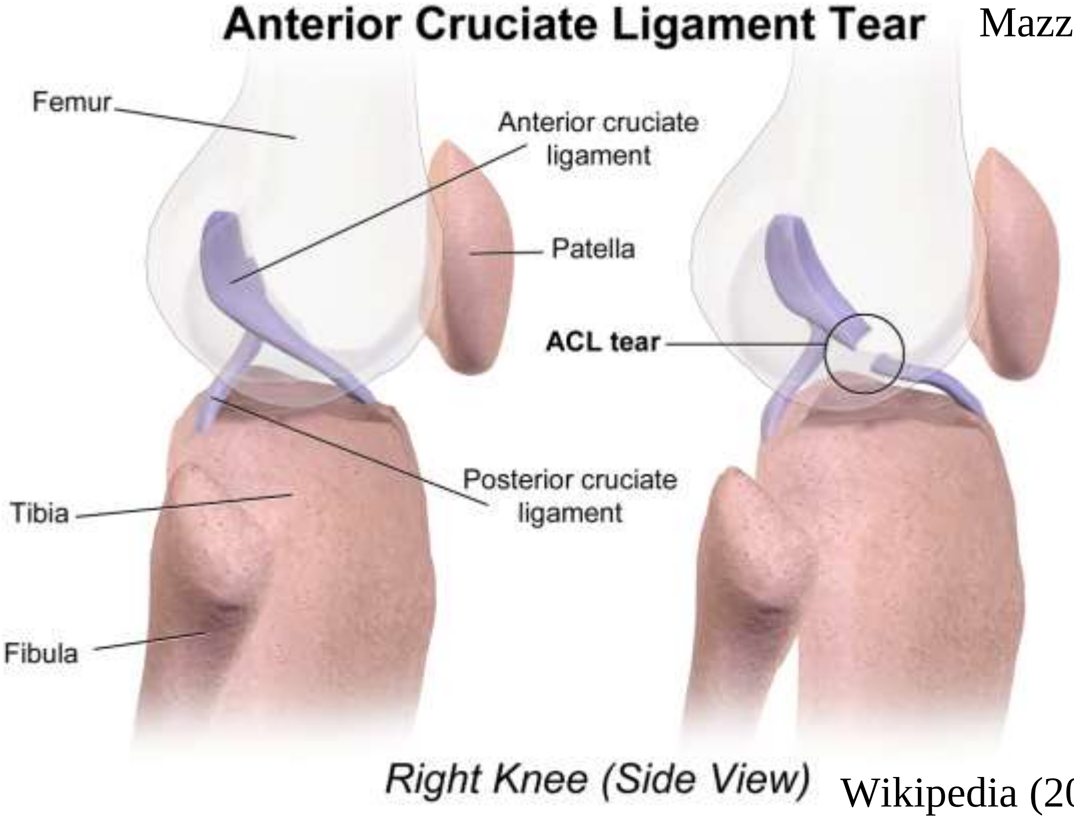
Front

Medical Images (2015)

The Tear - The ACL and Its Properties

An Anterior Cruciate Ligament has a documented tear threshold of 2110 +/- 50 N

Mazzocca (2014)



Wikipedia (2015)

ACLIs Do Not Heal Themselves

- The Synovial Fluid
  - Non-Newtonian Fluid that reduces friction between the cartilage
- Effects the ACL healing process
  - Prevents blood from clotting on the torn ACL
  - Blood clotting acts like a reconstructive scaffold that facilitates scar tissue creation and healing.

HyrdaRub (2006)

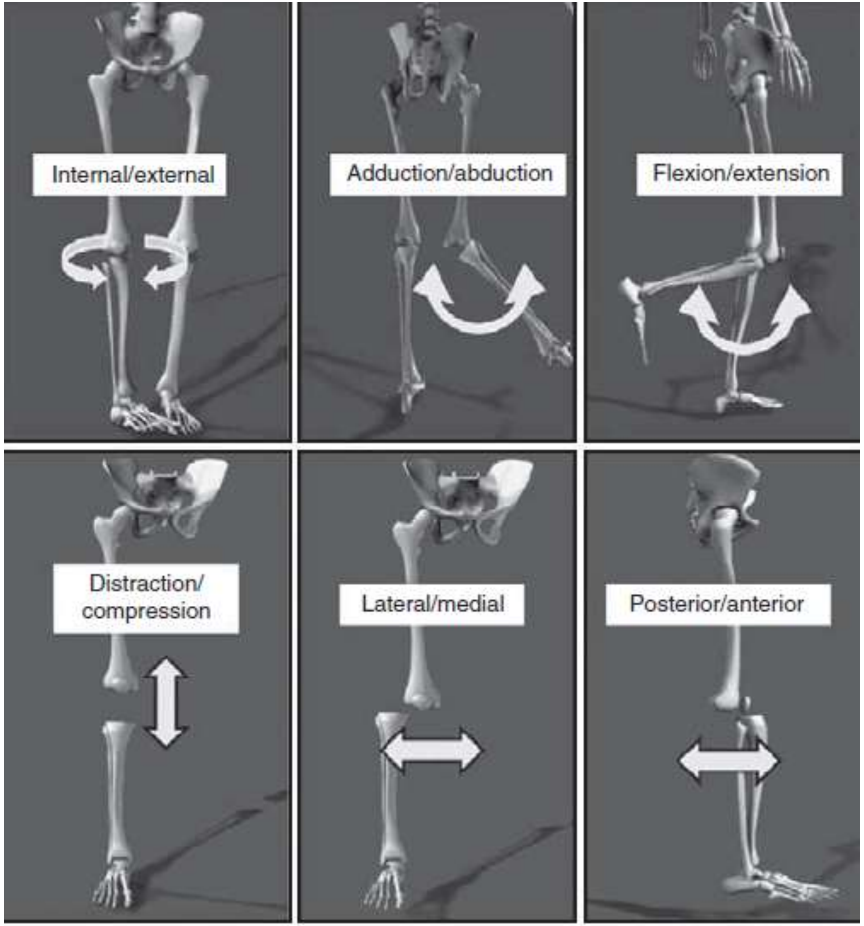
Dr. David Geier (2014)

It won't heal on its own.

Failure Mechanisms

NON-CONTACT

CONTACT



70%

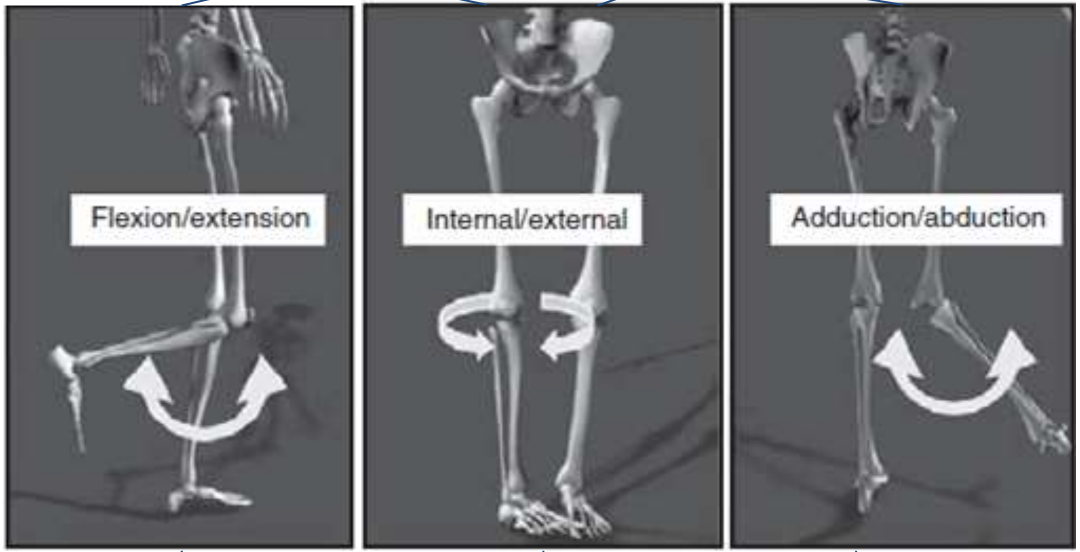
30%

Quatman (2010)

Non Contact Failure Mechanisms

1%

37%



78K Flexion Extension ACL Injuries per year

37%

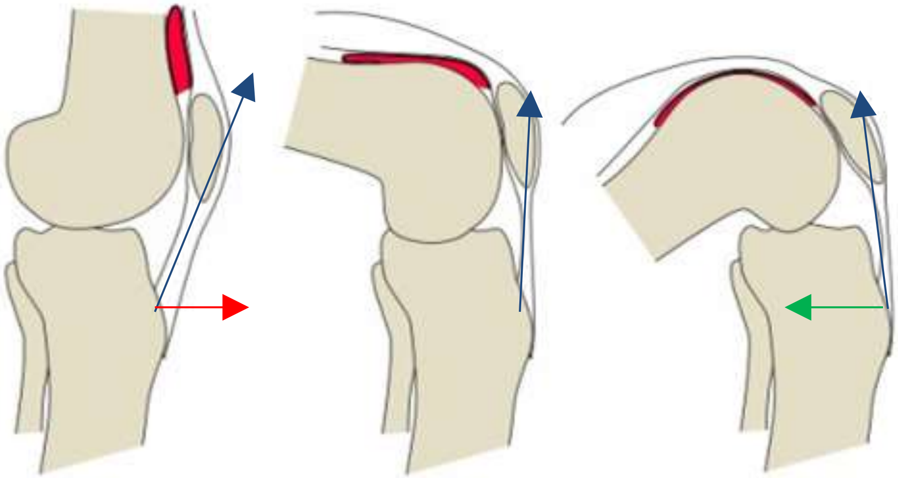
16%

9%

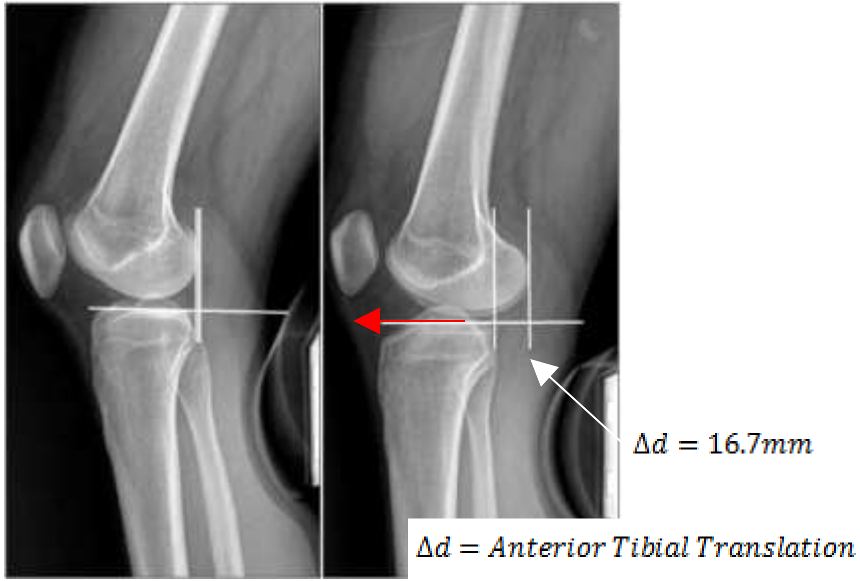
Shimokochi (2008)

Quatman (2010)

The Flexion Tear - TSF



Knee Anatomy <2016>



Lee <2011>

Current Identification and Mitigation

- Sterile Environment - Not Dynamic
- Need a Trainer
- Given prior to or after exposure to injury
- Not many coaches follow it 30%
  Norcross (2015)

	Cost	Duration	Frequency
Central Texas Pediatric Orthopedics (2015)	$300	6 weeks	3x per week
Estimate Per School Year	$1,800	36 weeks	3x per week

The Gap

Gap 1: Identify Strain

There is no method to actively quantify ACL strain

Gap 2: Mitigate Strain

There is no method to actively mitigate the probability of an ACL injury during real time

Stakeholder Analysis

Stakeholders	As-is	To-be
Athlete	Chance of tearing ACL	Chance of tear decreases by 25%
Surgeon	Reconstruct ACL	Less need for reconstruction
Physical Therapist	Rehabilitate Athlete	Less need for rehabilitation
Team	Lose chemistry and substitutes	Remains whole
Athletic Gear Manufacturers	Shoes, tape, clothing, etc.	Create a Market

Problem Statement

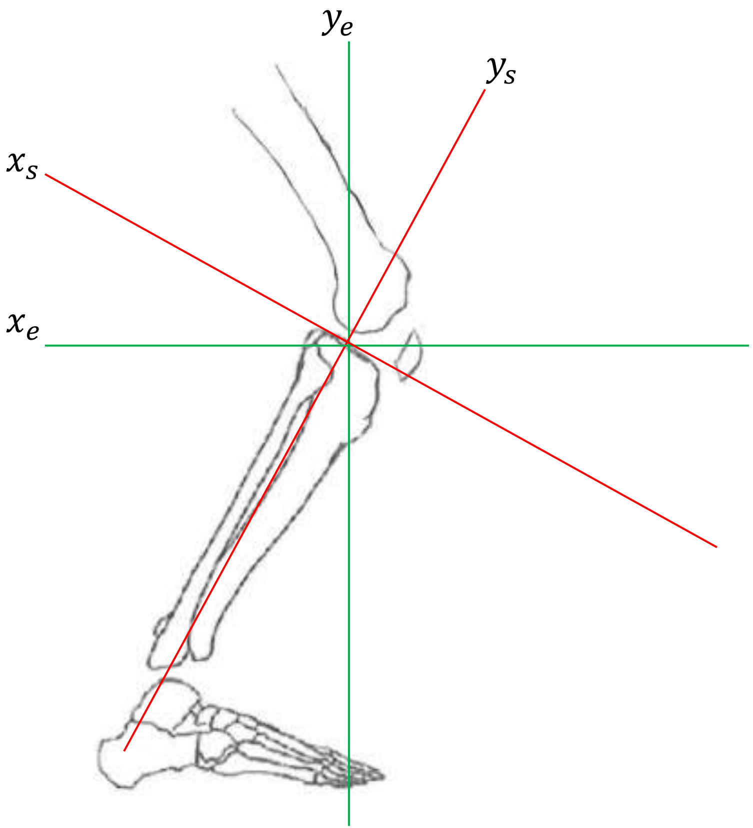
There are 300K anterior cruciate ligament tears every year, of which, 78K are flexion / extension related. And there is no system that currently quantifies and mitigates strain.

Need Statement

There needs to be a precise system that quantifies the strain on an anterior cruciate ligament and gives the athlete a chance to mitigate the situation and reduce the probability of tear by at least 20%.

Method of Analysis

Reference Frame



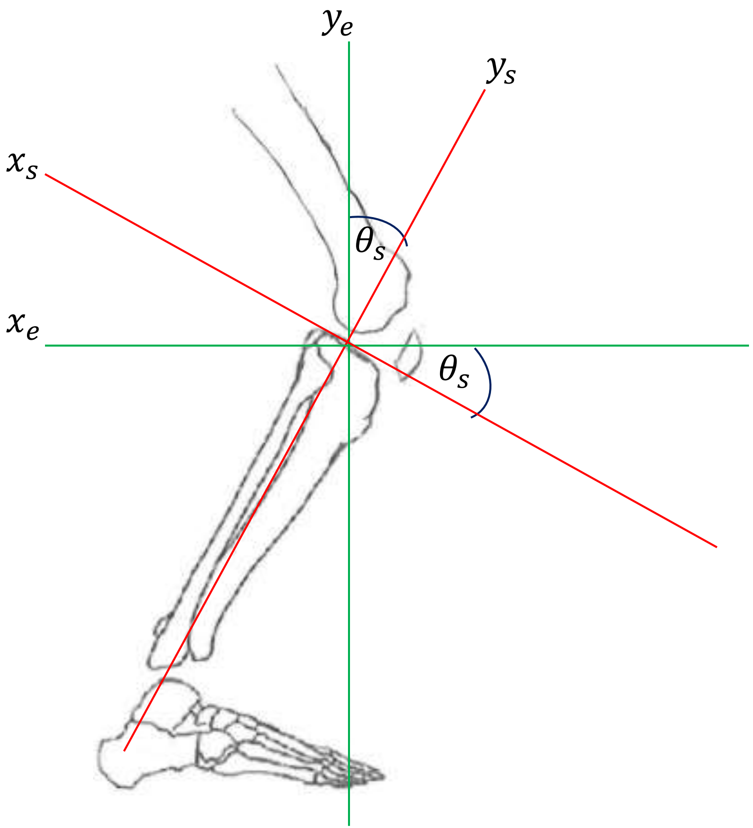
x_e = x-axis of the earth

y_e = y-axis of the earth

x_s = x-axis of the shank

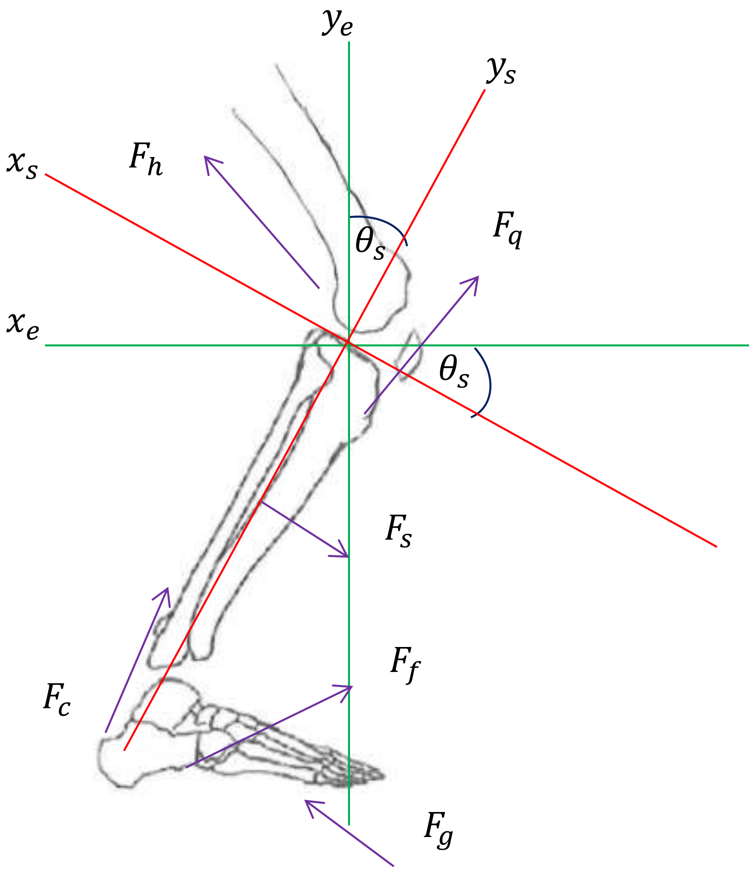
y_s = y-axis of the shank

Angles



x_e = x-axis of the earth
y_e = y-axis of the earth
x_s = x-axis of the shank
y_s = y-axis of the shank
θ_s = shank angle

Forces



x_e = x-axis of the earth
y_e = y-axis of the earth
x_s = x-axis of the shank
y_s = y-axis of the shank
θ_s = shank angle
F_f = Foot Force
F_s = Shank Force
F_g = Ground Reaction Force
F_q = Quadriceps Force
F_h = Hamstring Force
F_c = Gastrocnemius Force

Tibial Shear Force - Tear At 2100 +- 50 N

$$TSF = F_{Shank} + F_{Foot} + F_{GroundReaction} + F_{Muscles}$$

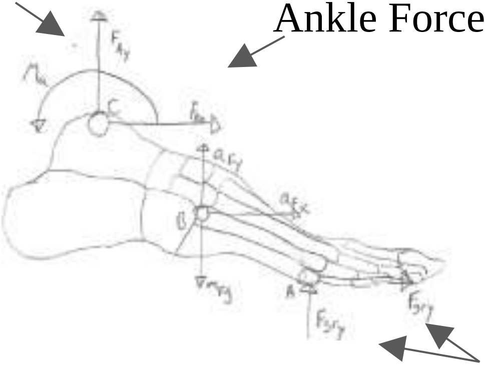
$$\begin{aligned} TSF = {} & m_s[a_{sx}\cos(\theta_s) - (a_{sy}+g)\sin(\theta_s)] \\ & + \mathrm{m_f}[\mathrm{a_{fx}}\cos(\theta_s) - (a_{fy}+g)\sin(\theta_s)] \\ & - G_{rfx}\cos(\theta_s) + G_{rfy}\sin(\theta_s) \\ & - \sum F_{GastroX} - \sum F_{QuadX} - \sum F_{HamX} \end{aligned}$$

Myers (2010)

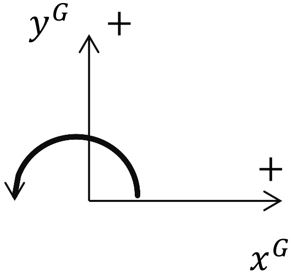
Foot Force to TSF Contribution

Ankle Force in the Y

Ankle Force in the X



Ground Reaction Forces



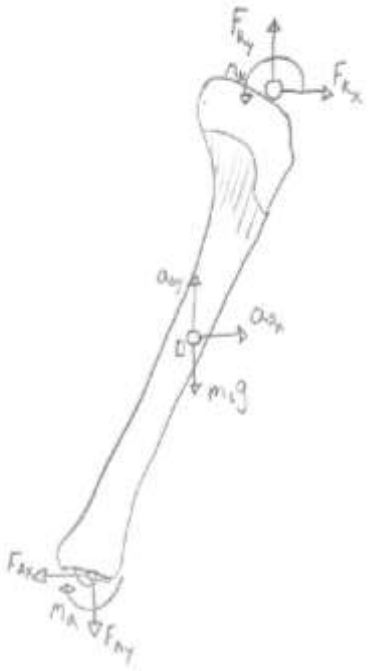
$$F_{Ax} = m_F a_{Fx} - R_x$$

$$F_{Ay} = m_F(a_{Fy} + g) - R_y$$

$$M_A = -R_y(X_{AB} - X_{CB}) + R_x(Y_B - Y_{CB}) - \left[m_F\left(a_{Fy} + g\right)\right](X_{CB}) + (m_F a_{Fx})(Y_{CB}) + I_F \alpha_F$$

Myers (2010)

Shank Force to TSF Contributions



$F_{Kx} = Foce\ of\ Knee\ in\ the\ X$

$F_{Ky} = Foce\ of\ Knee\ in\ the\ Y$

$F_{Ax} = Foce\ of\ Ankle\ in\ the\ X$

$F_{Ay} = Foce\ of\ Ankle\ in\ the\ Y$

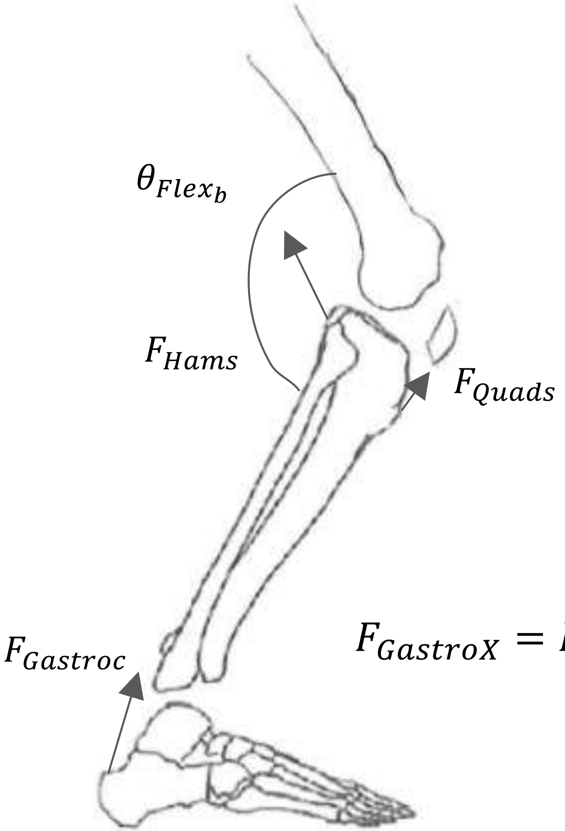
$$F_{Kx} = m_s a_{sx} + m_F a_{Fx} - R_x$$

$$F_{Ky} = m_s(a_{sy} + g) + m_F a_{Fy} - R_y$$

$$M_K = M_A - F_{Ay}(X_{DC}) + F_{Ax}(Y_{DC}) - F_{Ky}(X_{ED}) + F_{Kx}(Y_{ED}) + I_s \alpha_s$$

Myers (2010)

Muscle Force Contributions to TSF Based on Anatomy



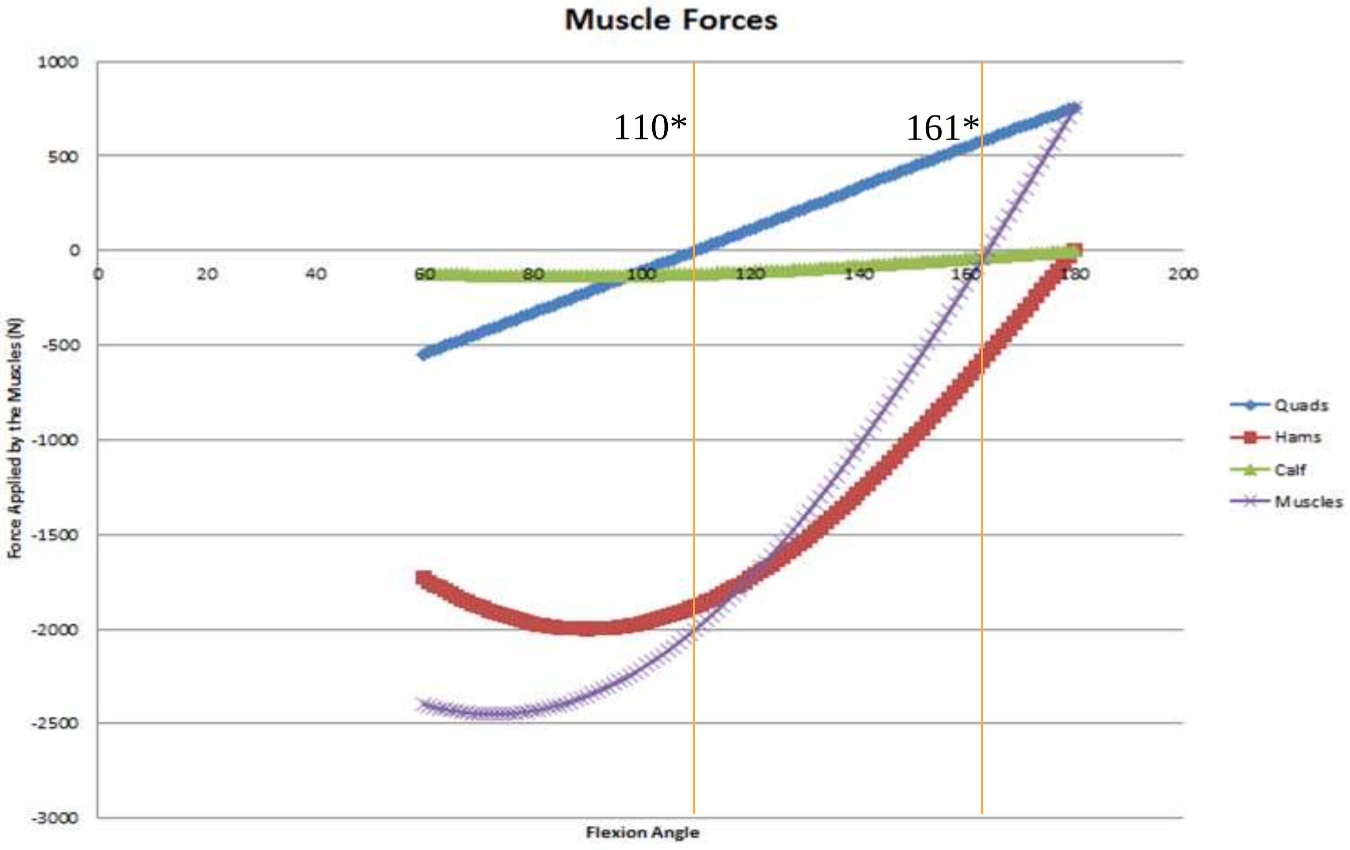
$$F_{QuadX} = F_{Quad}\sin((-.238)\left(180 - \theta_{flex_b}\right) + 22.2)$$

$$F_{HamX} = F_{Ham}\cos(90 - \theta)$$

$$F_{GastroX} = F_{Gastro}\sin(\sin^{-1}(\frac{(d)sin\left(\theta_{flex_b}\right)}{\sqrt{d^2 + tib_{length}^2 - (2)(d)\left(tib_{length}\right)\cos(\theta_{flex_b})}}))$$

Sensitivity Analysis on TSF Equations

Flexion Angle

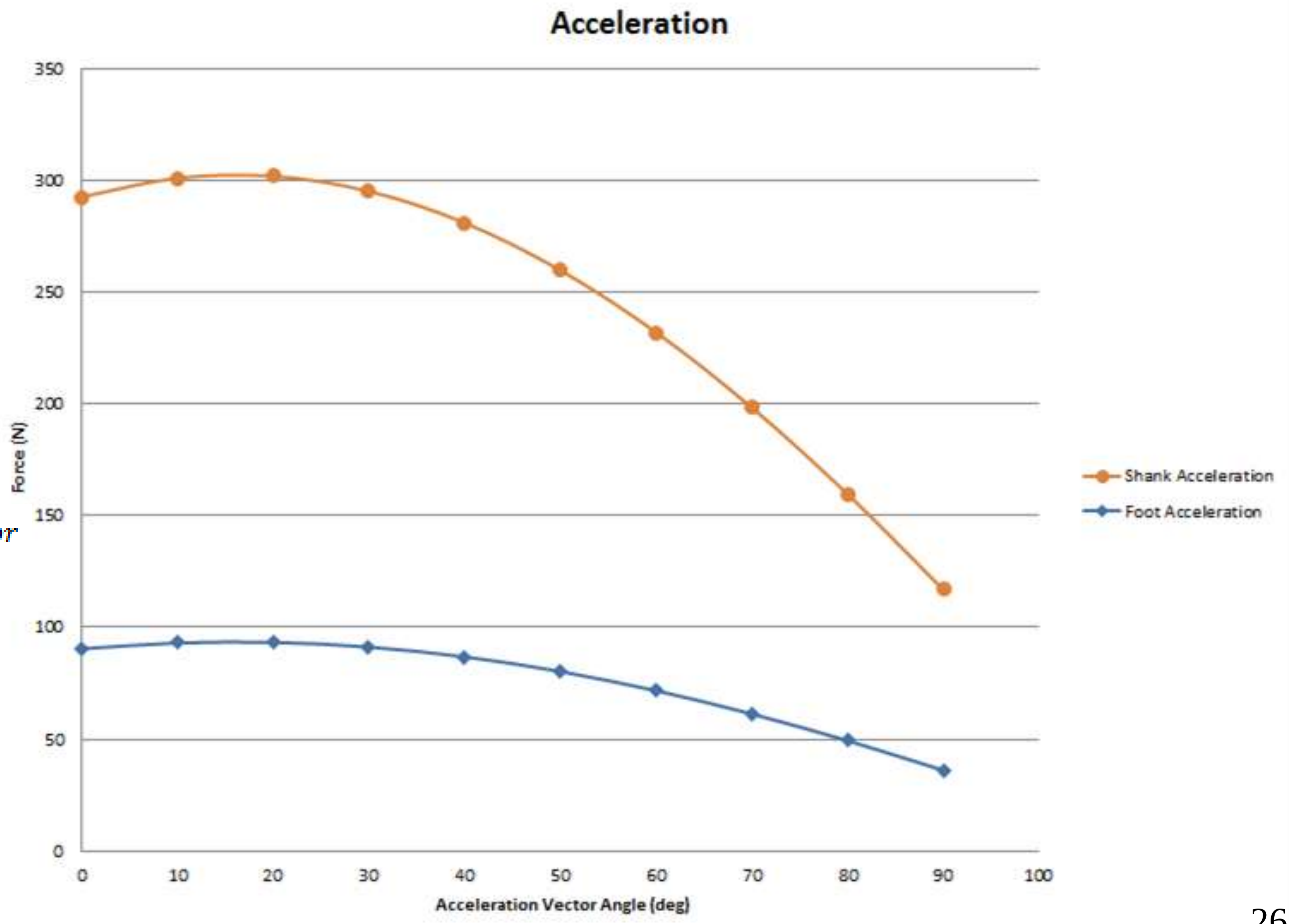


When Flexion is Above 161 degrees, that is known as Quad Dominant Form

Acceleration Of Foot and Shank Forces

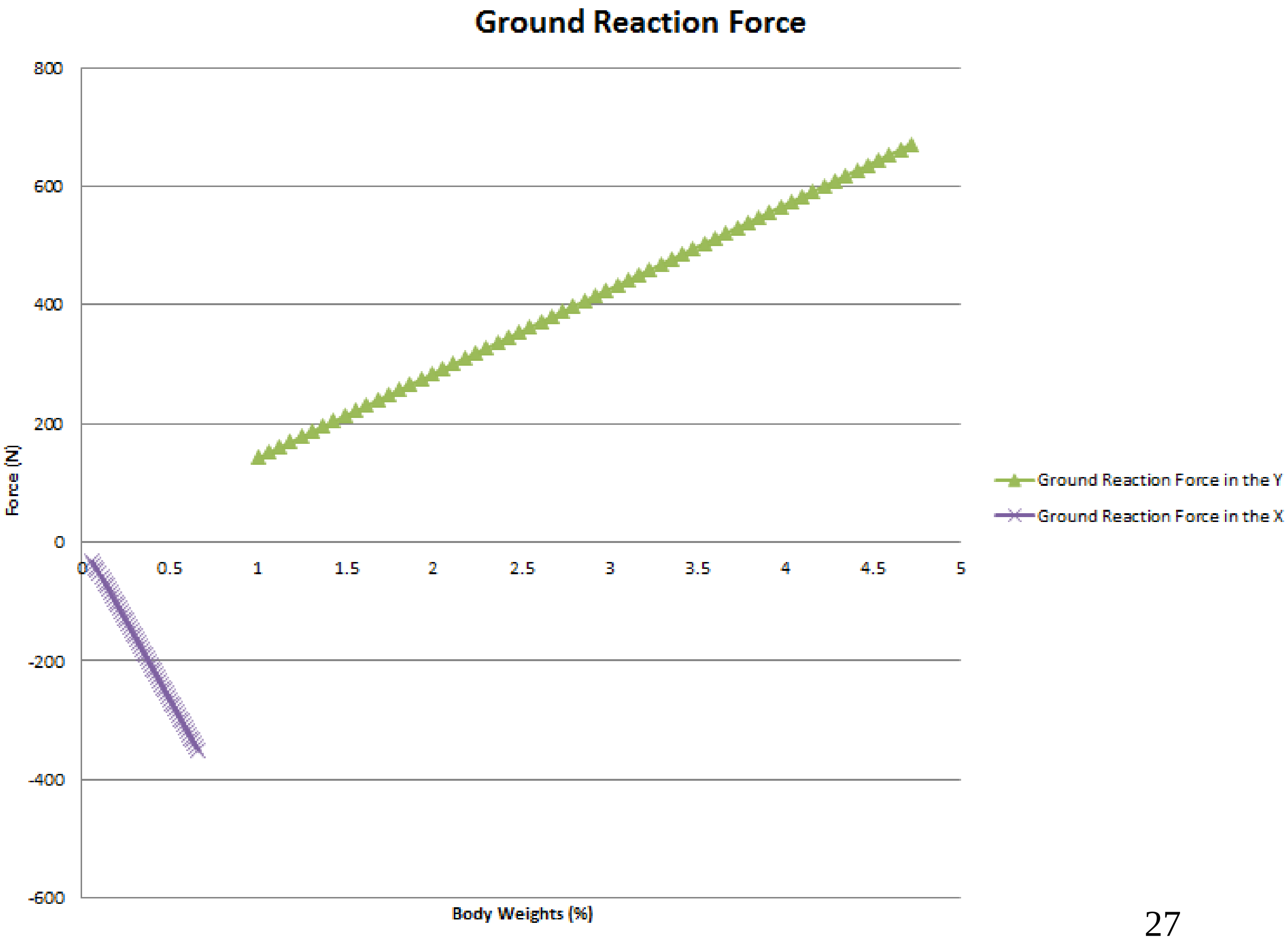
$\theta_{Shank} = 18°$

$Max\ TSF\ at\ 18°\ Acceleration\ Vector$



Ground Reaction Force in the X and Y Directions

Average female athlete with a 15 deg shank angle



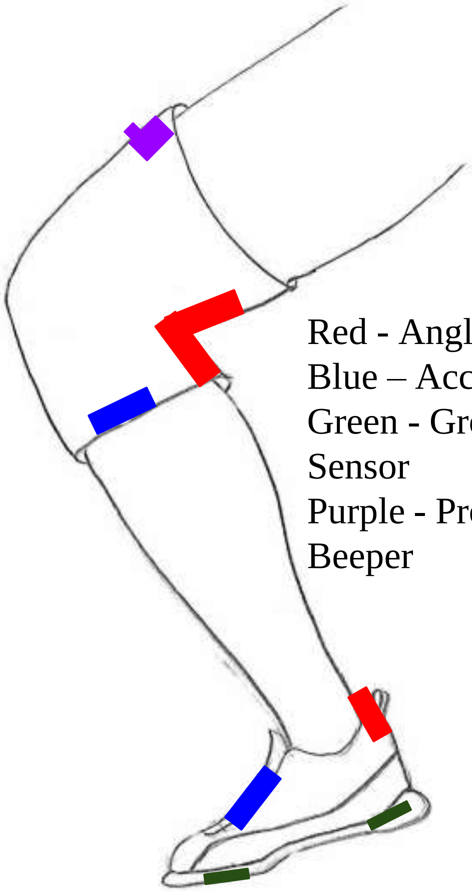
Tibial Shear Force - Tear At 2100 +- 50 N

$$TSF = F_{Shank} + F_{Foot} + F_{GroundReaction} + F_{Muscles}$$

$$\begin{aligned} TSF = {} & m_s[a_{sx}\cos(\theta_s) - (a_{sy} + g)\sin(\theta_s)] \\ & + \mathrm{m_f}[\mathrm{a_{fx}}\cos(\theta_s) - (a_{fy} + g)\sin(\theta_s)] \\ & - G_{rfx}\cos(\theta_s) + G_{rfy}\sin(\theta_s) \\ & - \sum F_{GastroX} - \sum F_{QuadX} - \sum F_{HamX} \end{aligned}$$

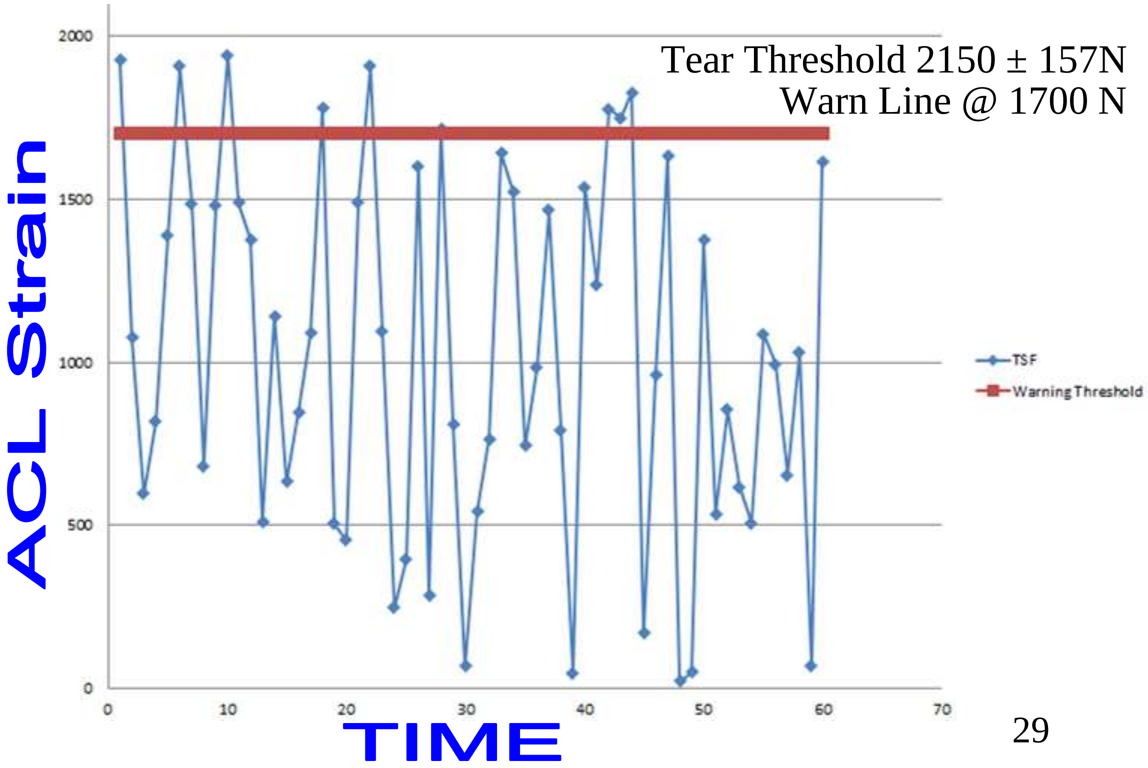
Myers (2010)

Solution



Red - Angle Sensor
Blue – Accelerometer
Green - Ground Reaction Sensor
Purple - Processor and Beeper

Biofeedback Active Sensor System (BASS)



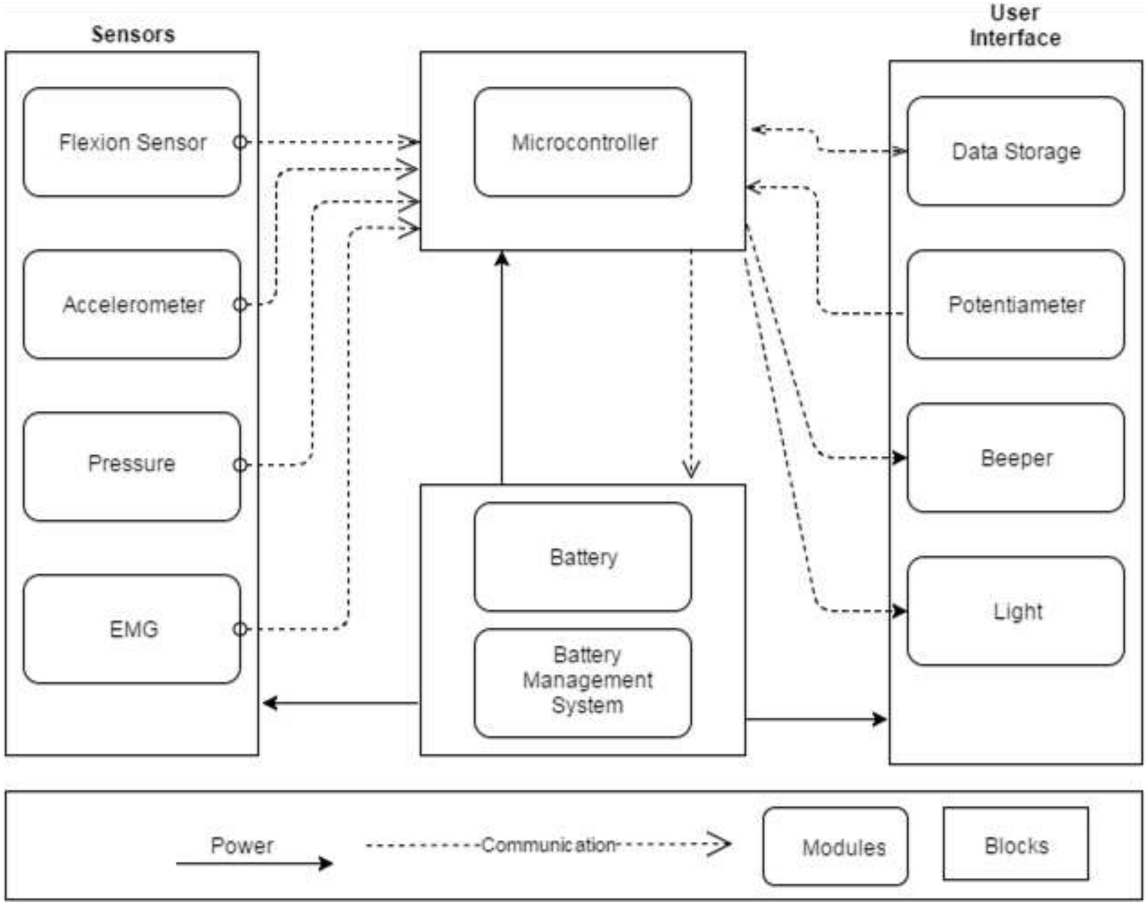
Requirements - Mission

Number	Requirement
M.1	The system shall warn the user of increased probability of ACL tear.
M.2	The system shall warn quantify ACL strain.
M.3	The system shall lower the number of ACL injuries by 20%
M.4	The system shall have a return on investment (ROI) after 1 year.

Requirements Functional

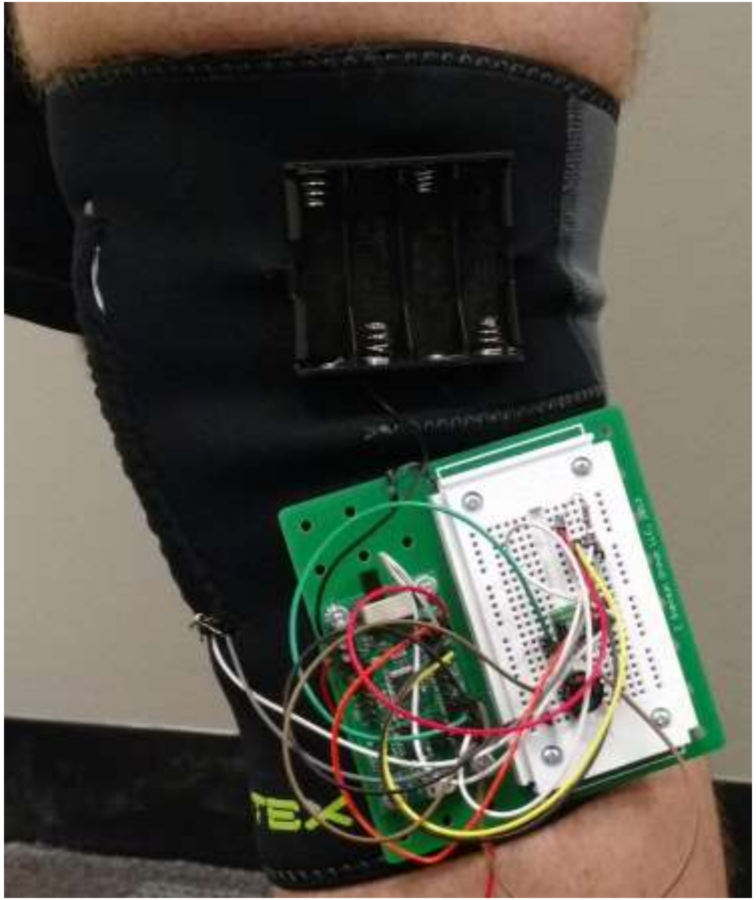
Number	Requirement
F.1	The system shall calculate the tibial shear force.
F.2	The system shall acquire data from the sensors.
F.3	The system shall translate the data into usable form.
F.4	The system shall measure the ground reaction force in the x and y directions.
F.5	The system shall measure the shank angle.
F.6	The system shall measure the acceleration of the foot in the x and y directions.
F.7	The system shall measure the acceleration of the shank in the x and y directions.
F.8	The system shall measure flexion angle.
F.9	The system shall warn of TSF greater than the warning threshold.
F.10	The system shall be able to be worn during exercise.
F.11	The system shall not deter performance.

Component Diagram



Design of Experiment

Input		**Output**
Flexion	Ground Reaction	**Beeping**
< 20 Deg	Low	**No**
< 20 Deg	High	**Yes**
> 20 Deg	High	**No**
> 20 Deg	Low	**No**



Requirements – Design Processor

Number	Requirement
D.5	The processor shall have specific measurements.
D.5.1	The processor shall have a length of less than 3 inches.
D.5.2	The processor shall have a width of less than 2.5 inches.
D.5.3	The processor shall have a weight less than 30 grams.
D.5.4	The processor shall have an operating voltage of at least 5 volts.

Requirements – Design Beeper

Number	Requirement
D.6	The beeper shall have specific measurements.
D.6.1	The beeper shall warn the user at greater than 85 dBA.
D.6.2	The beeper shall weigh less than 5 grams.

Requirements – Design Flexion

Number	Requirement
D.4	The flexion sensor shall have specific measurements.
D.4.1	The flexion angle sensor shall have a length of less than 1.3 inches.
D.4.2	The flexion angle sensor shall have a width of less than 1.2 inches.
D.4.3	The flexion angle sensor shall have an accuracy of at least 99%.
D.4.4	The flexion angle sensor shall have a precision of at least 95%.
D.4.5	The flexion angle sensor shall be able to read angles as low as 0 degrees.
D.4.6	The flexion angle sensor shall be able to read angles as high as 180 degrees.
D.4.7	The flexion angle sensor shall be no more than 50 grams.

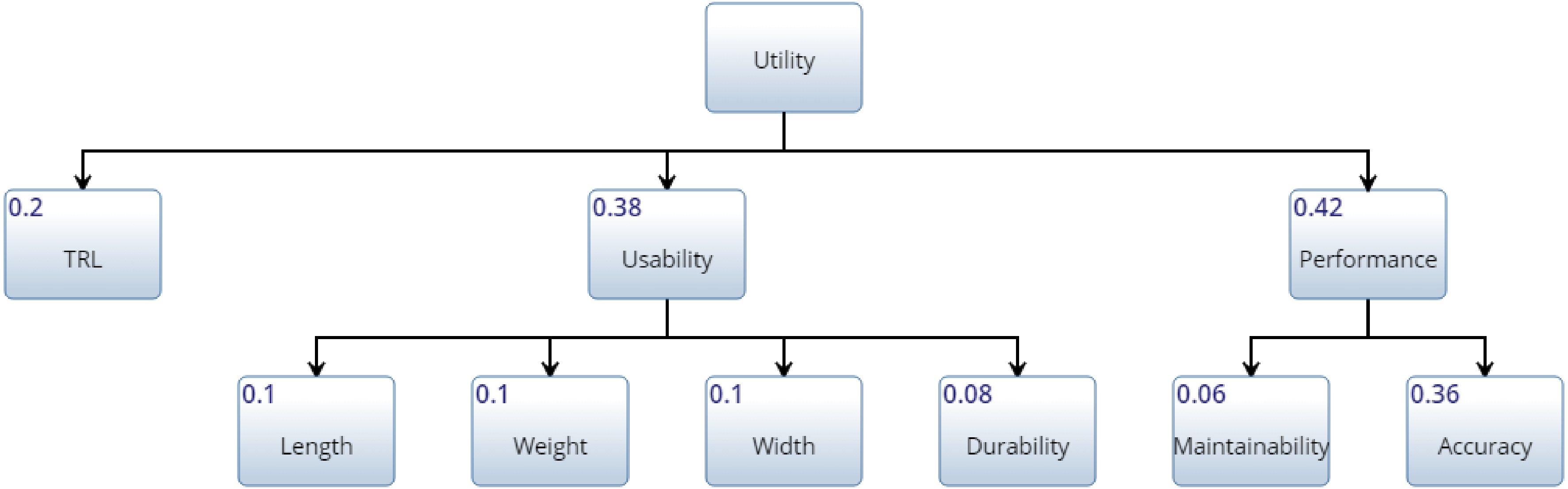
Requirements – Design Ground Reaction

Number	Requirement
D.2	The ground reaction force sensor shall have specific measurements.
D.2.1	The ground reaction force sensor shall have a length of less than 1.5 inches.
D.2.2	The ground reaction force sensor shall have a width of less than 1.3 inches.
D.2.3	The ground reaction force sensor shall have an accuracy of at least 92% in the x and z components.
D.2.4	The ground reaction force sensor shall have an accuracy of at least 90% in the y component.
D.2.5	The ground reaction force sensor shall have a precision of at least 95%.
D.2.6	The ground reaction force sensor shall read forces up to 2100 newtons.
D.2.7	The ground reaction force sensor shall weigh less than 50 grams.

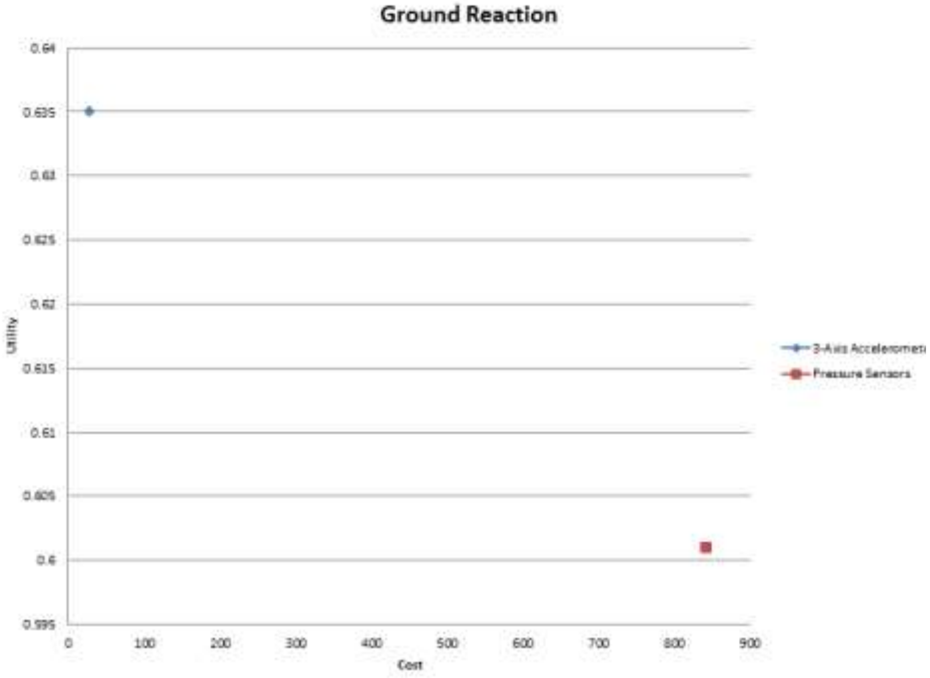
Requirements – Design Accelerometer

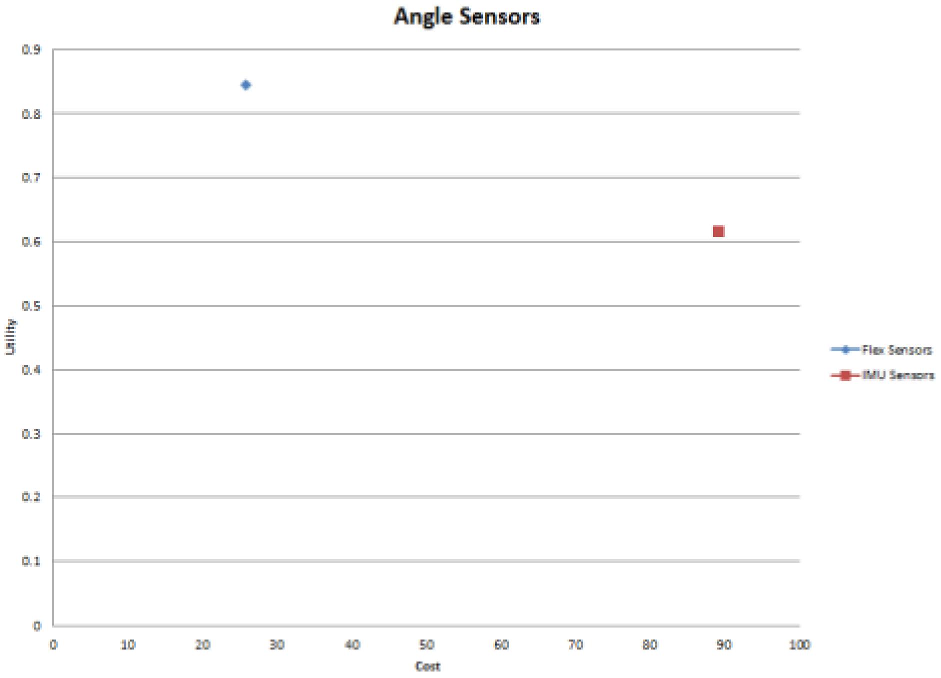
Number	Requirement
D.3	The accelerometer shall have specific measurements.
D.3.1	The accelerometer shall have a length of less than 5 mm.
D.3.2	The accelerometer shall have a width of less than 5 mm.
D.3.3	The accelerometer shall have an accuracy of at least 95%.
D.3.4	The accelerometer shall have a precision of at least 95%.
D.3.5	The accelerometer shall be able to read acceleration as low as .03 m/s^2.
D.3.6	The accelerometer shall be able to read acceleration as high as 80 m/s^2.
D.3.7	The accelerometer shall be able to read 3 axes.

Value Hierarchy



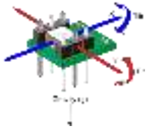
Utility Vs Cost



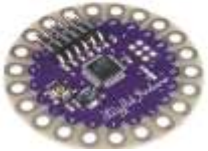


System Components

Variable Measured	Unit	Length	Width	Accuracy	Weight	Cost
Flexion and Shank	Flex Sensor	2.2 in	0.25 in	93% Masadar (2013)	0.5 g	$12.95
Ground Reaction Force	3-axis Accelerometer	0.87 in	0.3 in	96% Pouliot-Laforte (2014)	0.5 g	$8.50
Acceleration	3-axis Accelerometer	0.83 in	0.71 in	97% Han (2014)	1.3 g	$7.95



Processor	Length	Width	# of Digital I/O Pins	# of Analog Input Channels	Weight	Cost
Wearable Microcontroller Board	2 in	2 in	14	6	5.67 g	$19.95



Business Case

Market Size - $600 M

Market:

1) ACLI Sufferers in the last 5 years = 300K injuries/year* 5 years
2) 420K NCAA Athletes <NCAA, 2015>
3) 18K Professional Athletes

Industry sector count	1.98 M
Selling Price	300
Total Market Value	**$593 M**

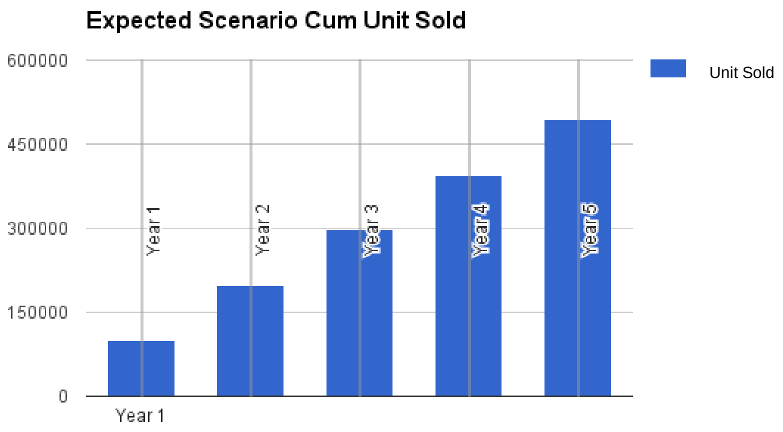
Scenarios	Expected	Pessimistic	Optimistic
% Market Share	**25%**	10%	50%
Penetration Rate	**5%**	2%	10%
Market Share Value	**$148 M**	$59 M	$297 M

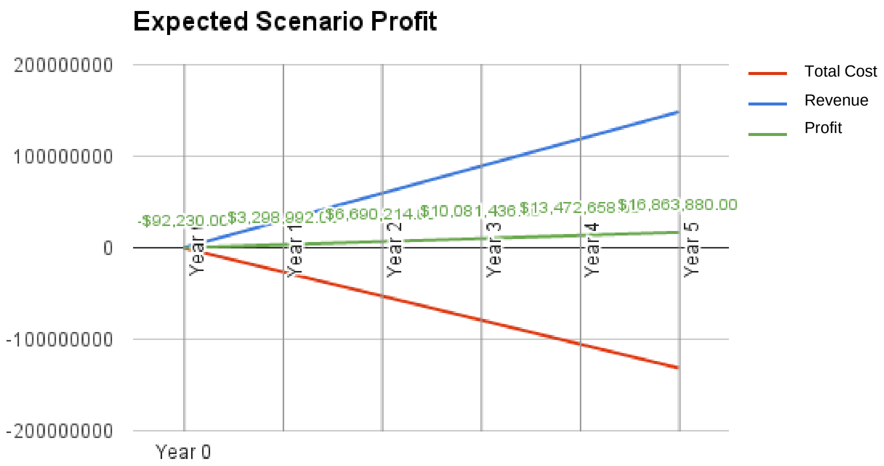
Costs & Initial Investment

Startup Costs		
Costs	Amount per unit	Description
Market Research (non-recurring cost)	3331	20 test product * cost of producing 1 unit
Overhead	63,200	Rent, Utilities, Health Ins
Rent + Utilities	54,000	$30/square feet* 1800 square feet
Utilities	6000	500/month*12 months
Health Insurance	3200	4 employees * cost of insurance/year
Marketing	20,000	
Website Development (non-recurring cost)	5640	visual design, programming, content support, client training
Signing for webhost	59.4	$4.95/month*12 month
Total Startup Cost	**92 K**	

Operational Costs		
Component Acquisition Costs	Amount	Description
Potentiometer X2	0.34	Measures threshold
Knee Sleeves X2	4	Wearable component
Pressure Sensors X16	127.2	Measures Ground Reaction Force
Speakers X2	0.94	Beeps When 1900 N is reached
Accelerometers X2	1.02	Measures Acceleration
Processor	19.95	Process input and make calculations
Flexion Sensor X4	51.8	Measures Knee Flexion
Total Cost	**204**	
Labor	20	hourly rate
Total Variable Costs	307851.2	Maximum Production for 4 employees*cost of components + labor cost * number of workers
Fixed costs	83,259	
Overhead	63,200	Rent, Utilities, Health Ins, Marketing
Marketing	20,000	
Webhost	59.4	
Total Operational Costs	**391 K**	

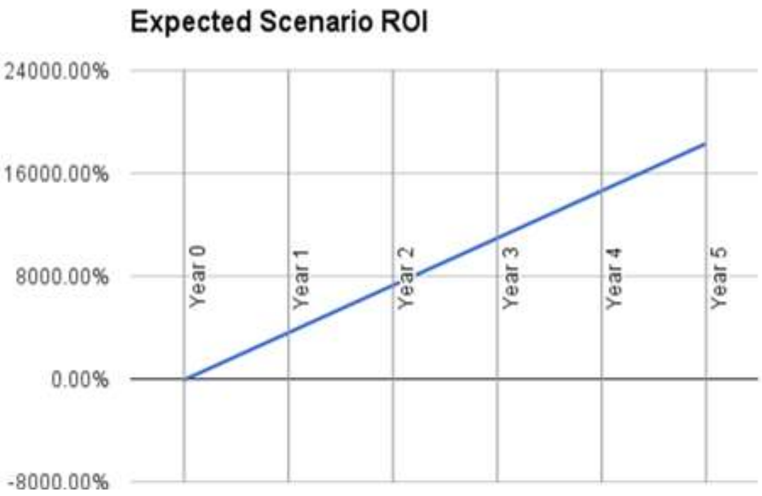
Expected Scenario Projection

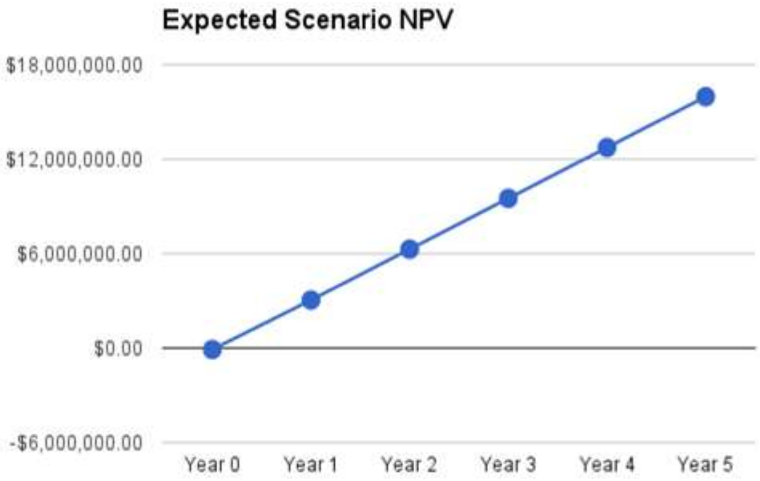




	Year 2	Year 5
Units Sold	197 K	494 K
Profit	$6.7 M	$17 M

Expected Scenario NPV & ROI



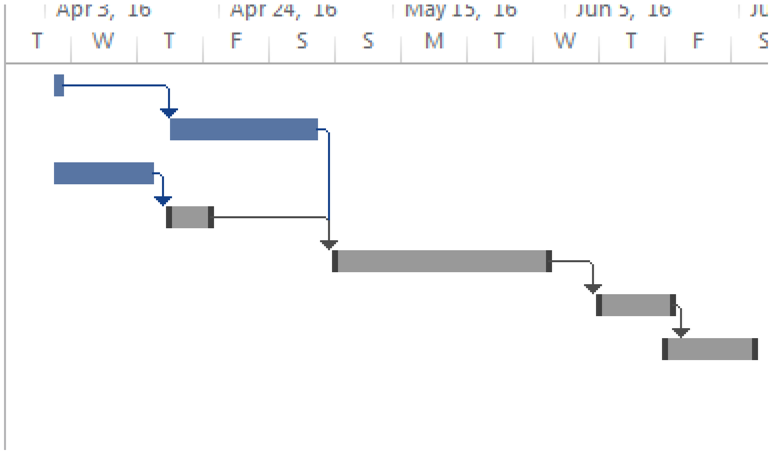


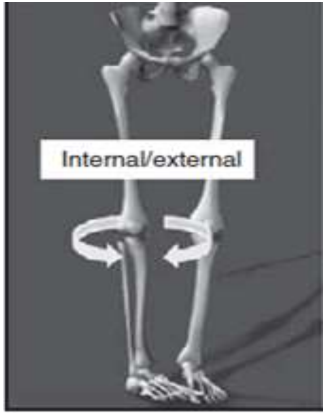
	Year 2	**Year 5**
NPV	$3 M	$16 M
ROI	3.6 K %	18 K %
Breakeven Point	3 Months (First Quarter)	

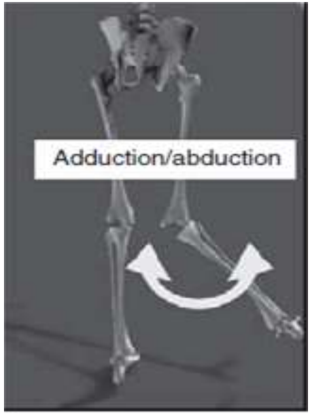
Reccomendations

Prototype Project Plan

Task Name	Duration	Start	Finish
Order Components	1 day	Mon 4/4/16	Mon 4/4/16
Component Testing	14 days	Mon 4/18/16	Thu 5/5/16
Java Coding	10 days	Mon 4/4/16	Fri 4/15/16
Software Testing	5 days	Mon 4/18/16	Fri 4/22/16
BASS System integration	20 days	Sun 5/8/16	Thu 6/2/16
Prototype Verification Testing	7 days	Thu 6/9/16	Fri 6/17/16
Prototype Validation Testing By Gait Analysis	7 days	Fri 6/17/16	Mon 6/27/16

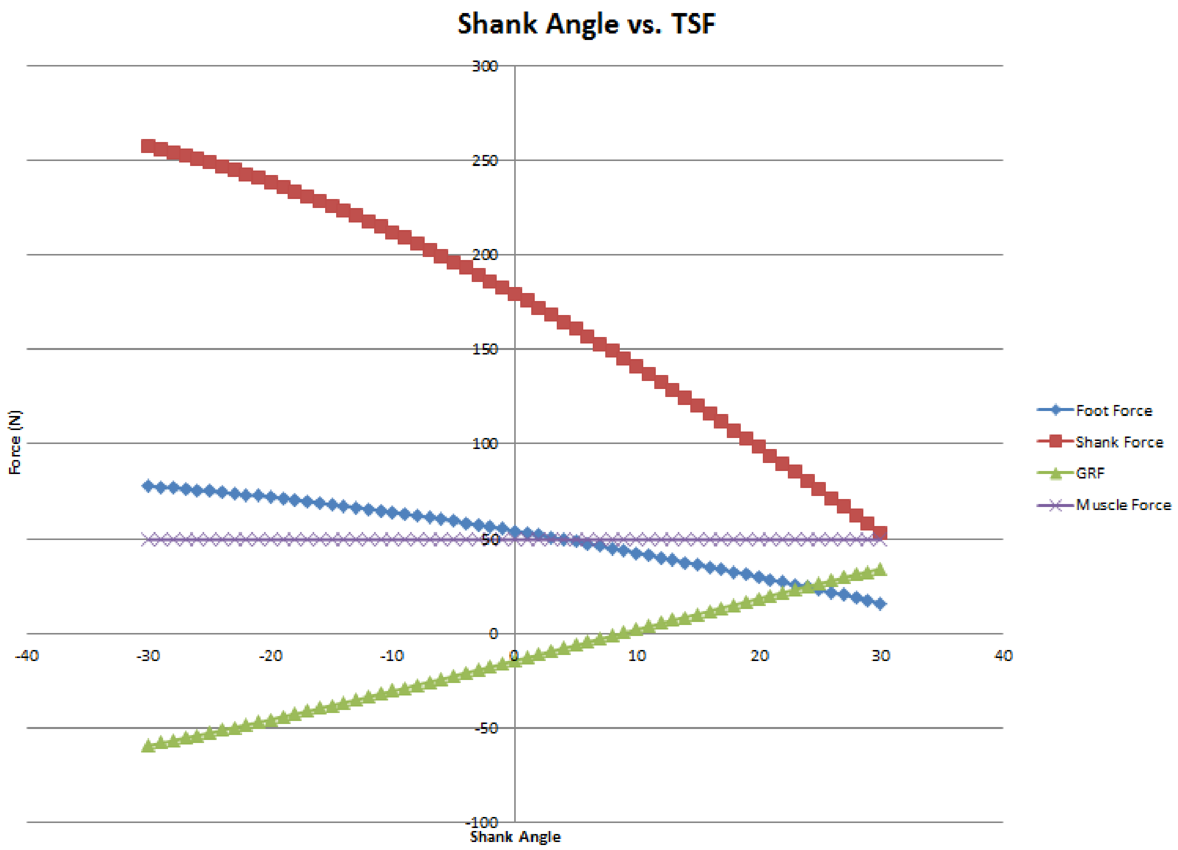






Back Up Slides

Shank Angle



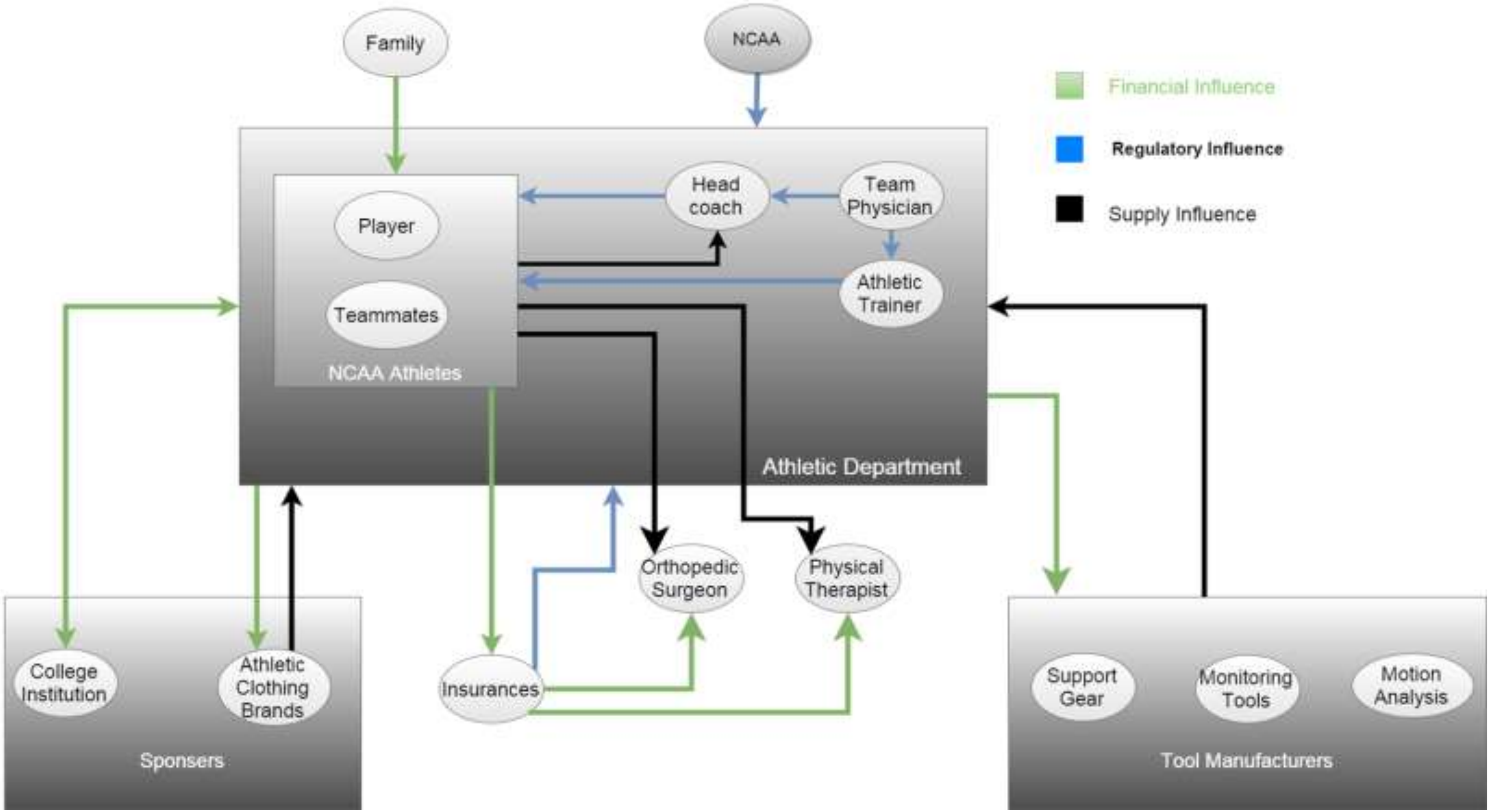
Shank Angle vs. TSF
300
250
200
150
100
50
0
-50
-100
-40
-30
-20
-10
0
10
20
30
40
Force (N)
Shank Angle
Foot Force
Shank Force
GRF
Muscle Force

Derivation of Ranges for Variables

Ranges Of Variables	Low	High	Derivation Method
Mass of Body	36.29	158.76	Range of athletes (female gymnast to male linemen)
Mass of Foot	0.50	2.19	de Leva <1996>
Mass of Shank	1.83	8.02	de Leva <1996>
Angle of Shank	-30	+ 30	Derived From Video Analysis and Anatomy
Acceleration of Shank in X	-84.93	82.77	Experiment
Acceleration of Shank in Y	-75.69	61.05	Experiment
Acceleration of Foot in X	-78.4	76.7	Experiment

Ranges Of Variables	Low	High	Derivation Method
Acceleration of Foot in Y	-77	69.15	Experiment
Reaction Force in X	0	.66	Meyers <2010>
Reaction Force in Y	1	4.74	Meyers <2010>
Flexion Angle	60	180	Anatomy
Quadriceps Force	266.7	1166.9	Wei <2016>
Hamstring Force	176.0	770.1	Wei <2016>
Gastrocnemius Force	346.7	1516.9	Wei <2016>

Stakeholder Analysis



Requirements – Design EMG

Number	Requirement
D.1	The muscle EMG sensor shall have specific measurements.
D.11.	The muscle EMG sensor shall have a length of less than 2.5 inches.
D.1.2	The muscle EMG sensor shall not have a width of less than 1 inch.
D.1.3	The muscle EMG sensor shall have an accuracy of at least 90%.
D.1.4	The muscle EMG sensor shall have a precision of at least 95%.