

# Issues of Human Interface design

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# Disclosures

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OPIE Software (Consultant)

AMR Medical (Consultant)

D-Rev Designs (Board of Advisors)

EK Health (Consultant)

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# SECTION ONE:

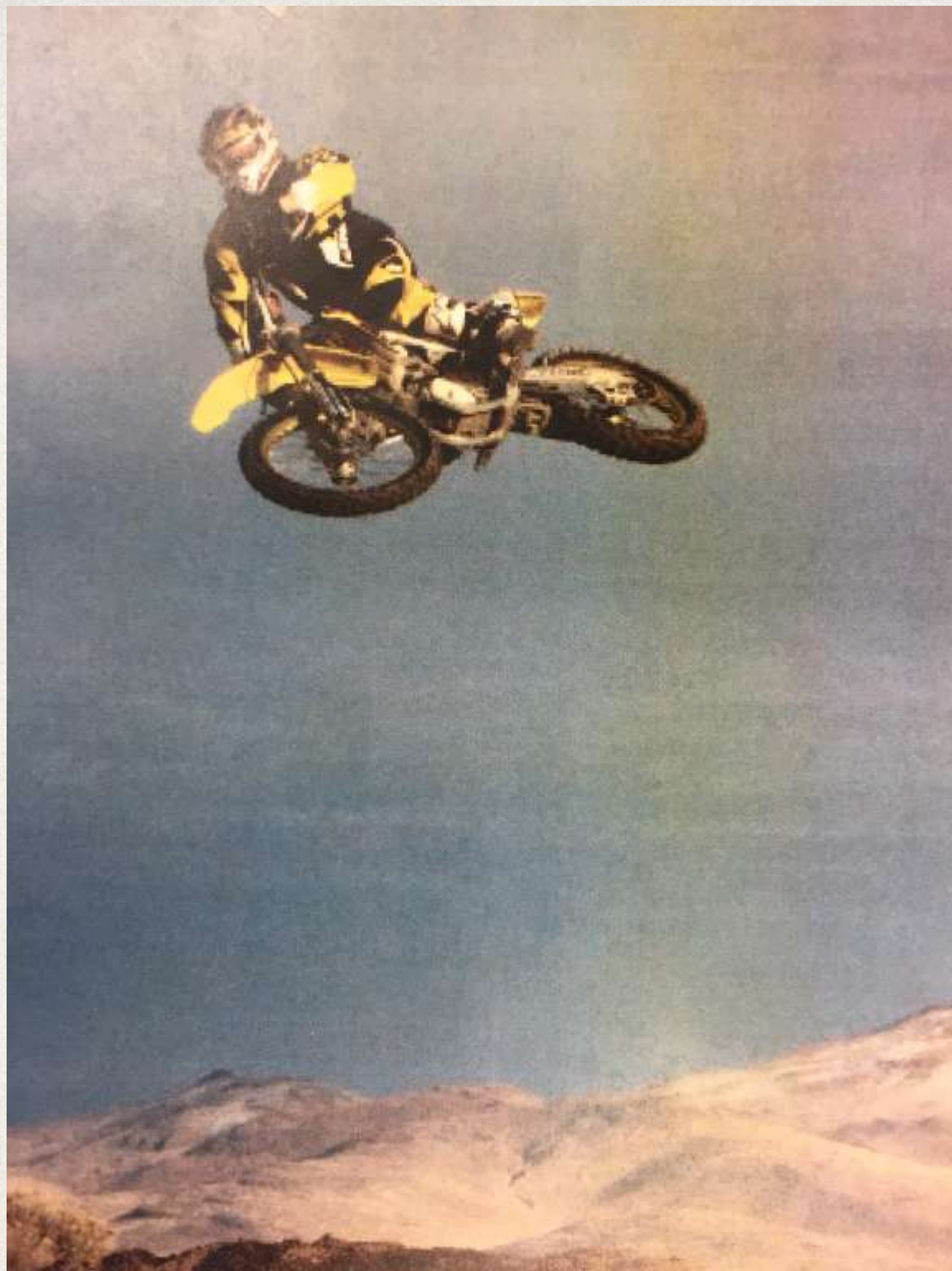
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The older I get the less I know.

















Stokes



ASSOCIATED PRESS





Better than human?

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## Section 2:

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# Designing for Humans



How do you design a  
shoe?







# Five C's

- Comfort
- Cosmesis
- funCtion
- Cost
- Cool





Better than Human?





Why are we so hell-bent  
on making people with  
amputations better  
than human,  
if we can't make  
able bodied people better  
than human??





Are elite runners getting faster or is a special pair of Nike shoes giving them an edge?











# Comfort

- ✱ Transference of pressure
- ✱ No “noxious” stimuli (noise, vibration etc)
- ✱ Heat
- ✱ Nuisance factor
  - ✱ easy to put on and take off
  - ✱ not too bulky
- ✱ Weight
- ✱ Sensitivity of skin or nerve



# Comfort

- ✱ What makes something comfortable?  
 $UN_{-}$
- ✱ Fluid dynamics, what happens when you add pressure to tissue?



# Comfort is elusive

- ✻ What may be “comfortable” one minute may not be the next.....



# funCtion

- Is it a device that reliably does what it is intended to do?



# funCtion

- ✱ Is there a device that can do everything?











# Cosmesis

• What is cosmetic?







# Cosmesis

- ✱ How do we perceive ourselves?
- ✱ How do changes to our body affect our perception of cosmesis?









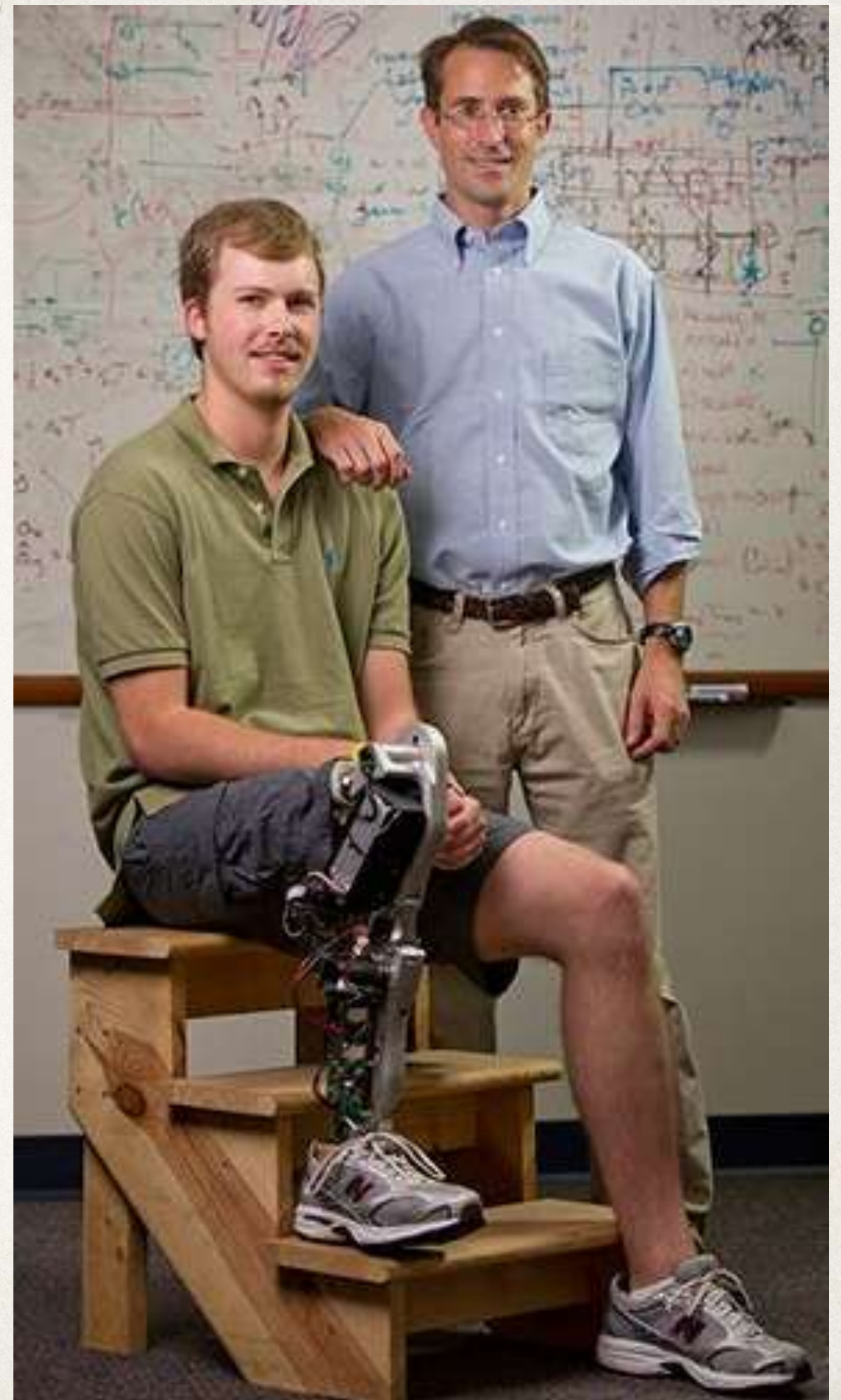






# Cost

- What is it worth to the consumer and...
- If it costs way more, does it provide a proportional improvement in comfort, function, cosmesis or cool?





# What does a prosthesis cost AND what do we get paid?







cool





“Cuz I deserve it”

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bionic

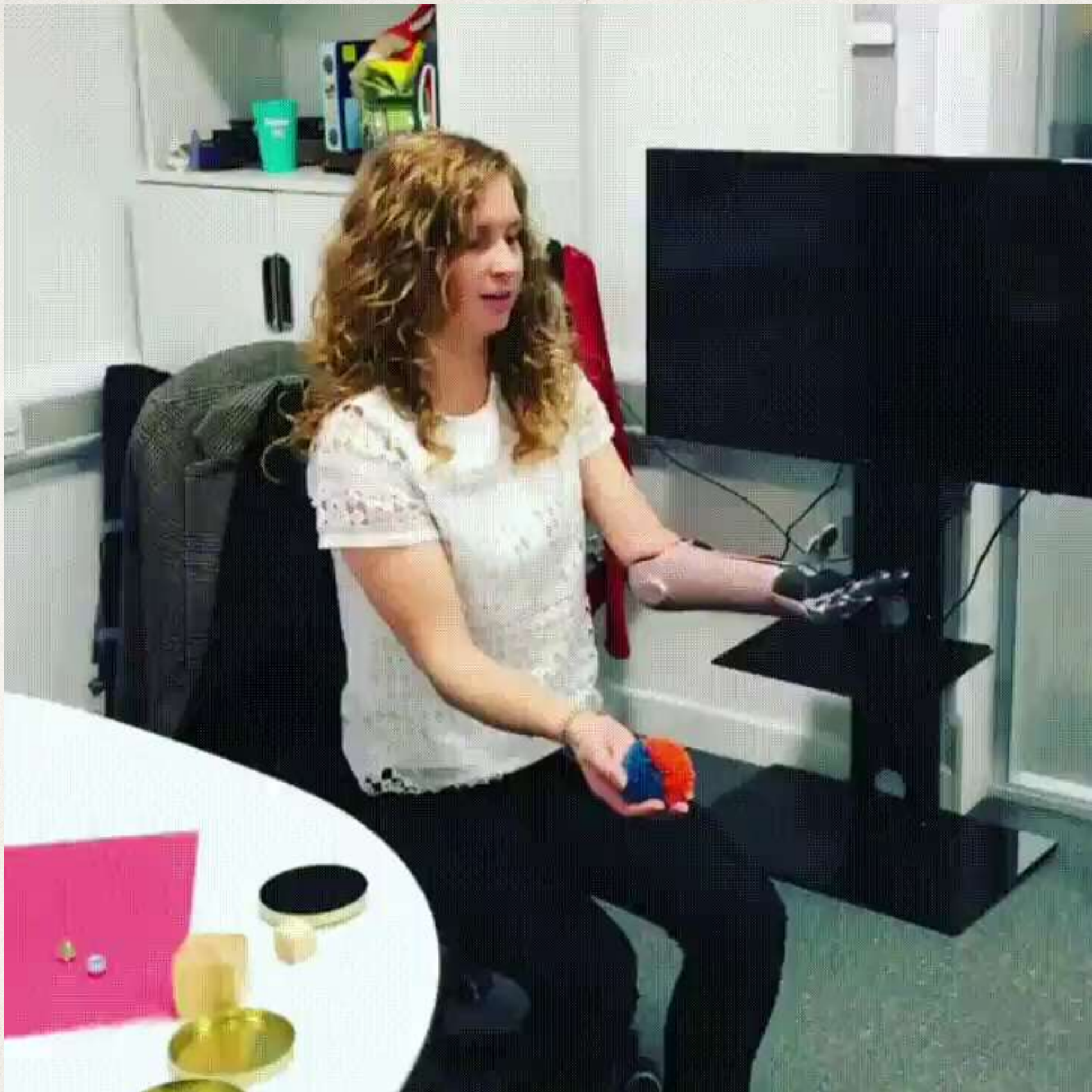






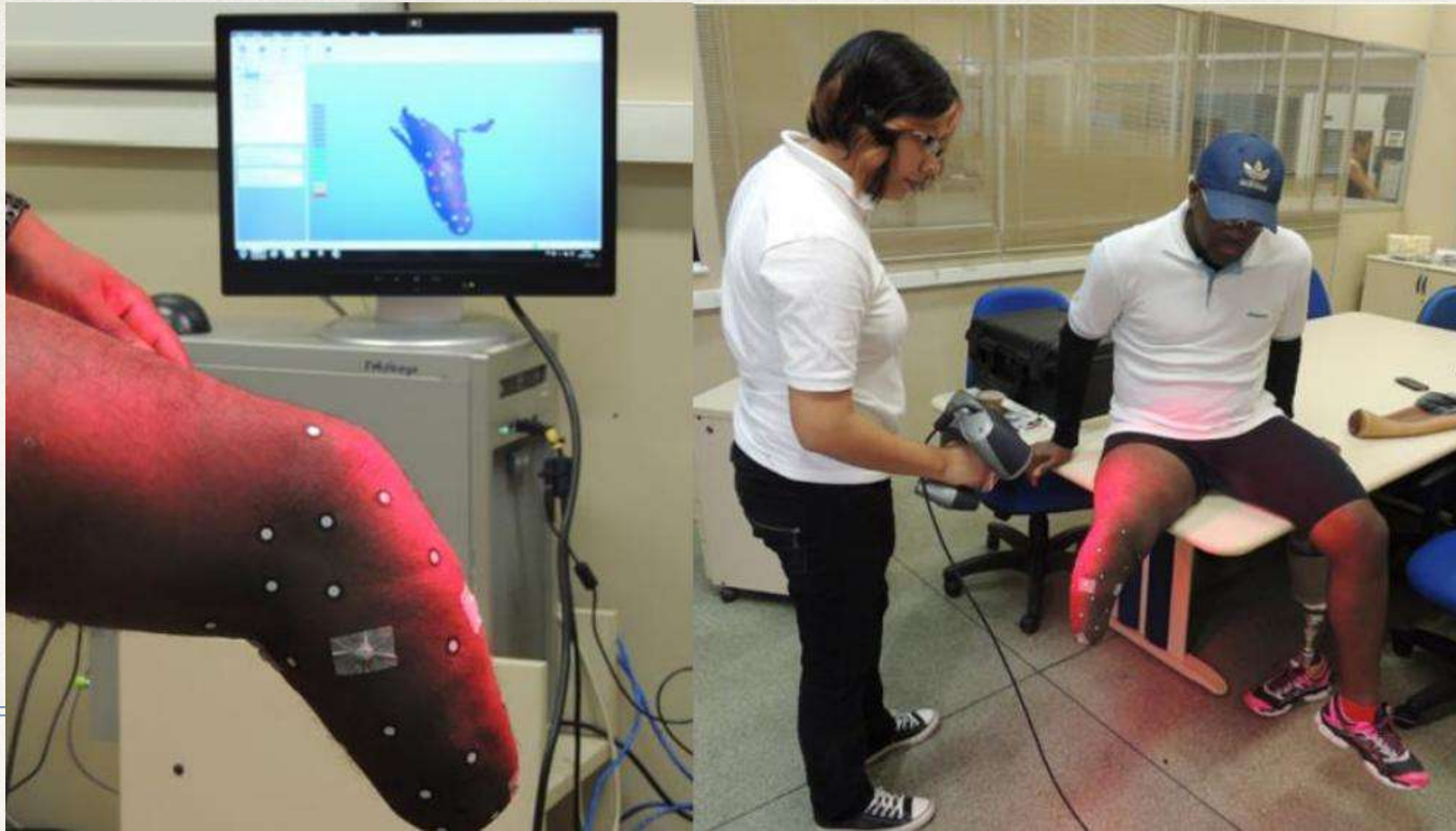






[Play  
video](#)





I give you permission to be  
skeptical with your optimism



# How do “things” interact with humans?

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glasses





	Regular glasses	Self Adjusting
Comfort	✓	
Function	✓	✓
Cosmesis	✓	
Cost	✓	
Cool		✓



# SECTION THREE:

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- ❖ There are people everywhere that use sticks to eat, perhaps we should 3-D print them forks.



# SECTION THREE:

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✿ Just because we CAN, doesn't mean  
we SHOULD







# How is a prosthesis made?

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As we have gotten significantly better and faster at building products, the challenge has shifted. The challenge today isn't building products, but uncovering what to build.



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## Section I. Directions for Taking Measurements and Diagrams of Single Leg Amputations (Right or Left)

### ONE LEG AMPUTATED IN OR ABOVE THE KNEE

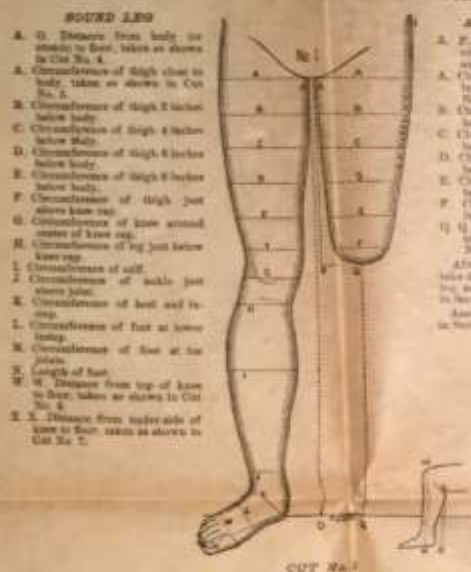
Distances and circumferences to be taken with a tape measure in the way indicated by illustrations in Section II. The figures to be placed on this cut.

### ONE LEG AMPUTATED BELOW THE KNEE, OR FOOT AMPUTATED AT THE ANKLE, OR INSTEP

Distances and circumferences to be taken with a tape measure in the way indicated by illustrations in Section II. The figures to be placed on this cut.

### ONE LEG AMPUTATED BELOW THE KNEE, LEAVING A VERY SHORT OR CONTRACTED STUMP, REQUIRING THE USE OF A KNEE-BEARING LEG

Distances and circumferences to be taken with a tape measure in the way indicated by illustrations in Section II. The figures to be placed on this cut.



**AMPUTATED LEG**

A. P. Distance from body to stump to foot, taken as shown in Cut No. 4.

B. Circumference of thigh close to body, taken as shown in Cut No. 5.

C. Circumference of thigh 2 inches below body.

D. Circumference of thigh 4 inches below body.

E. Circumference of thigh 6 inches below body.

F. Circumference of thigh just above knee cap.

G. Circumference of knee around center of knee cap.

H. Circumference of leg just below knee cap.

I. Circumference of calf.

J. Circumference of ankle just above joint.

K. Circumference of heel and instep.

L. Circumference of foot at lowest instep.

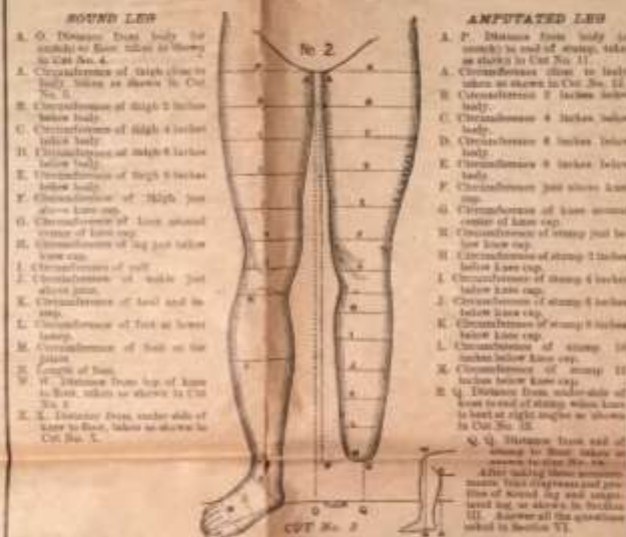
M. Circumference of foot at the joint.

N. Length of foot.

O. Distance from tip of knee to foot, taken as shown in Cut No. 6.

P. Distance from upper side of knee to foot, taken as shown in Cut No. 7.

After taking these measurements, take diagrams and profiles of sound leg and amputated leg, as shown in Section III. Answer all the questions asked in Section VI.



**AMPUTATED LEG**

A. P. Distance from body to stump to foot, taken as shown in Cut No. 4.

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L. Circumference of foot at lowest instep.

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## Section II. Illustrations Showing the Manner of Measuring



## Section III. Directions for Taking Diagrams and Profiles of Single Leg Amputations

Be seated in this position, or another about the same when the sound leg is to be measured. Directly upward. Draw a line from the hip to the foot, taken as shown in Cut No. 4. Draw the leg up close to the body as shown. Then Cut No. 5. Draw the leg up close to the body as shown. Then Cut No. 6. Draw the leg up close to the body as shown. Then Cut No. 7. Draw the leg up close to the body as shown. Then Cut No. 8. Draw the leg up close to the body as shown. Then Cut No. 9. Draw the leg up close to the body as shown. Then Cut No. 10. Draw the leg up close to the body as shown. Then Cut No. 11. Draw the leg up close to the body as shown. Then Cut No. 12. Draw the leg up close to the body as shown. Then Cut No. 13. Draw the leg up close to the body as shown. Then Cut No. 14. Draw the leg up close to the body as shown. Then Cut No. 15. Draw the leg up close to the body as shown. Then Cut No. 16. Draw the leg up close to the body as shown. Then Cut No. 17. Draw the leg up close to the body as shown. Then Cut No. 18. Draw the leg up close to the body as shown. Then Cut No. 19. Draw the leg up close to the body as shown. Then Cut No. 20. Draw the leg up close to the body as shown. Then Cut No. 21. Draw the leg up close to the body as shown.







CABINET

POCKET

PHOTOGRAPHED BY

*Bowman*

OTTAWA, CAN.

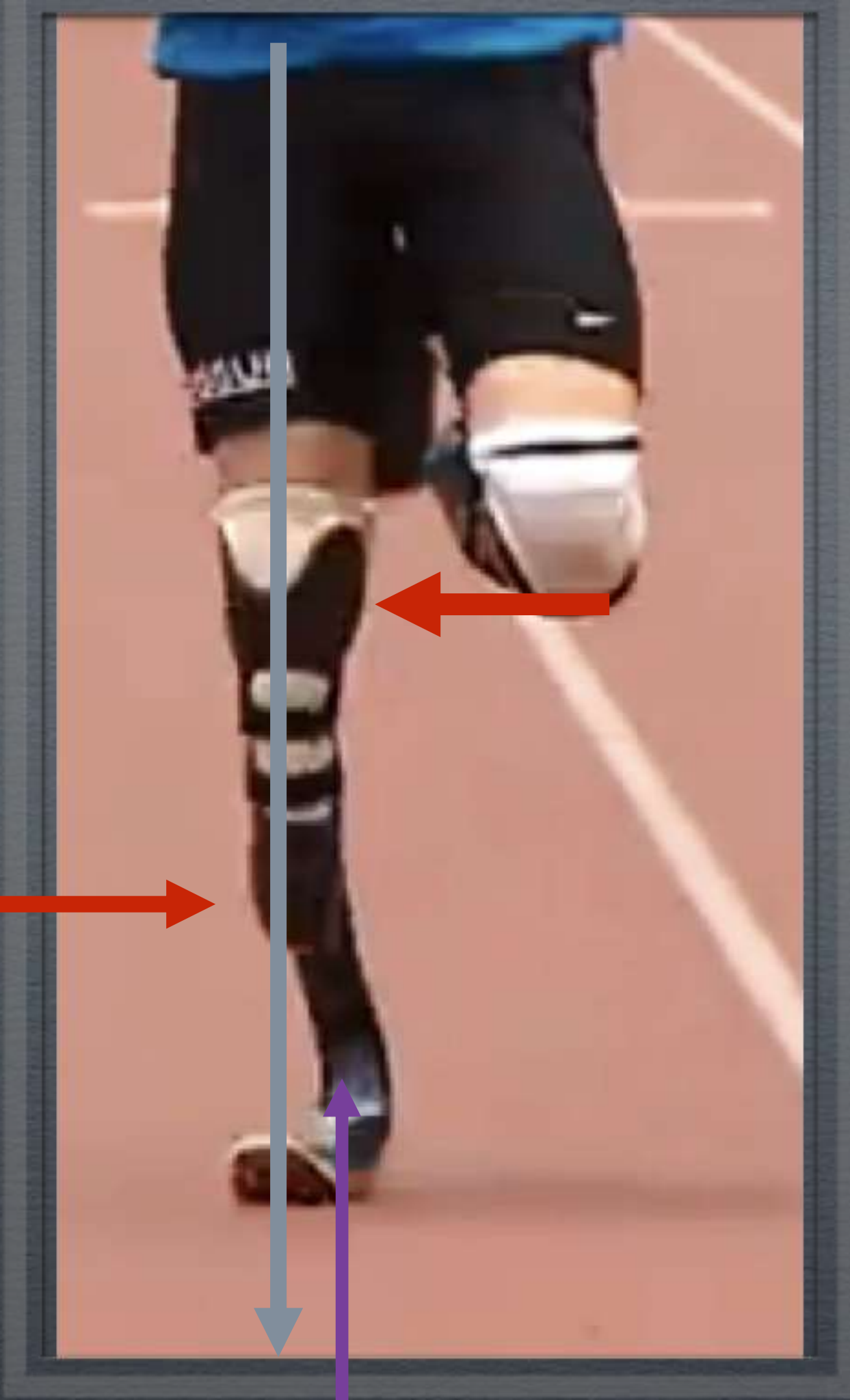


# Total Contact / Total Surface Bearing

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**A prosthesis must fit intimately enough to comfortably support the limb during high loading, not bother the soft tissues and bone and transfer motion from the human to the device with extreme efficiency.**





# SECTION FOUR:

## I have to do what??

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FDA, ISO, CE and other  
regulatory hurdles





# The US FDA defines Class 1:

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Not intended for use in supporting or sustaining life or of Substantial Importance in preventing impairment to human health, And they may not present a potential for unreasonable risk of illness or injury.



# Class 1 devices

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- ❖ Technical File
- ❖ Human studies
- ❖ Validation of safety and efficacy
- ❖ Human Factors Engineering



# ISO- International Standards Organization

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- ✦ ISO-10328
- ✦ 3m cycles
- ✦ Test to failure



# CE Mark

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- ❖ In order to go to “Market” in Europe
- ❖ Self Mark vs Serial number



You can't start with the technology and try to figure out where you're going to try to sell it.

Steve Jobs





HUMAN?

















# Total Contact/ Total Surface Bearing

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WEIGHT TO BE ENTERED

WEIGHT TO BE ENTERED

Service -



# SECTION FIVE:

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- ❖ It is hard when the expectation of the patient is greater than the design can provide.











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