

Issues of Human Interface design

Gary M. Berke MS, CP, FAAOP

Adjunct Clinical Associate Professor,
Department of Orthopaedic Surgery
Stanford University

Private Practitioner, Berke Prosthetics/
Orthotics, San Mateo, CA

Chief Clinical Officer,
Medical Creations LLC, Aspen CO



Disclosures

OPIE Software (Consultant)

AMR Medical (Consultant)

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EK Health (Consultant)

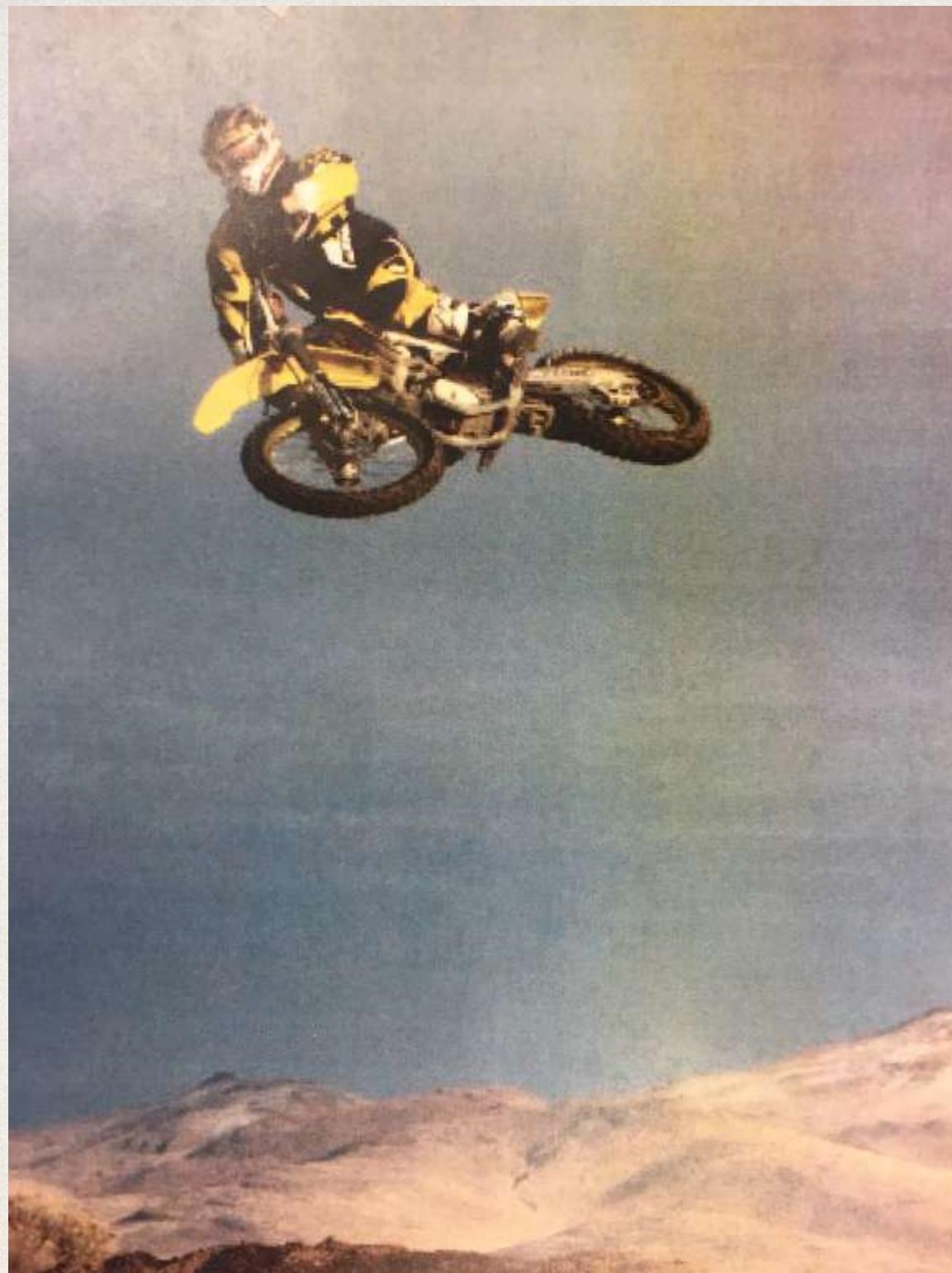
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SECTION ONE:

The older I get the less I know.









ASSOCIATED PRESS

Stokes



Better than human?

Section 2:

Designing for Humans

How do you design a
shoe?



Five C's

- Comfort
- Cosmesis
- funCtion
- Cost
- Cool



Better than Human?



Advanced
Binding

Knee cuffs

A-frame

Spring feet

Replaceable Foot pads

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?

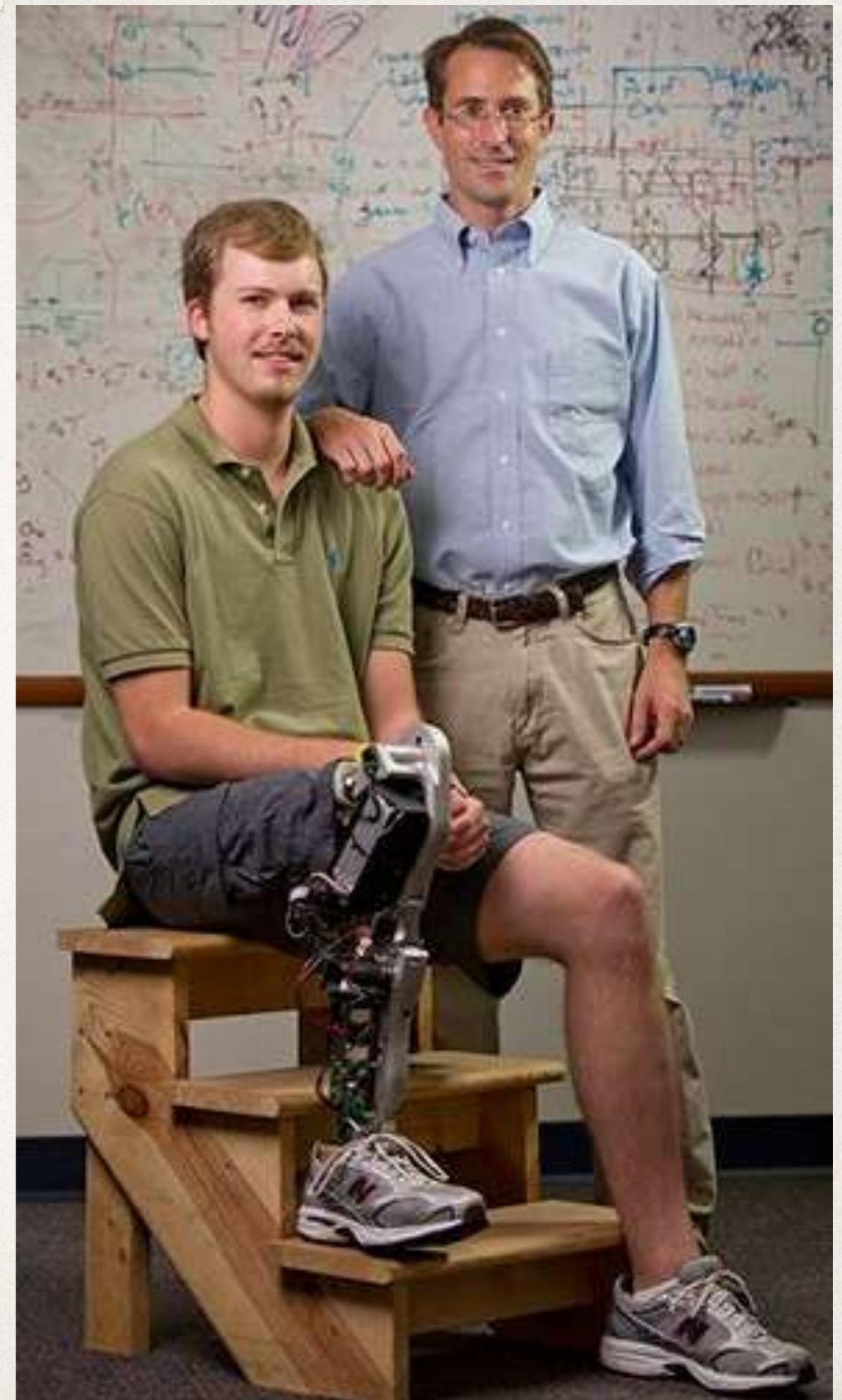






Cost

- 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?

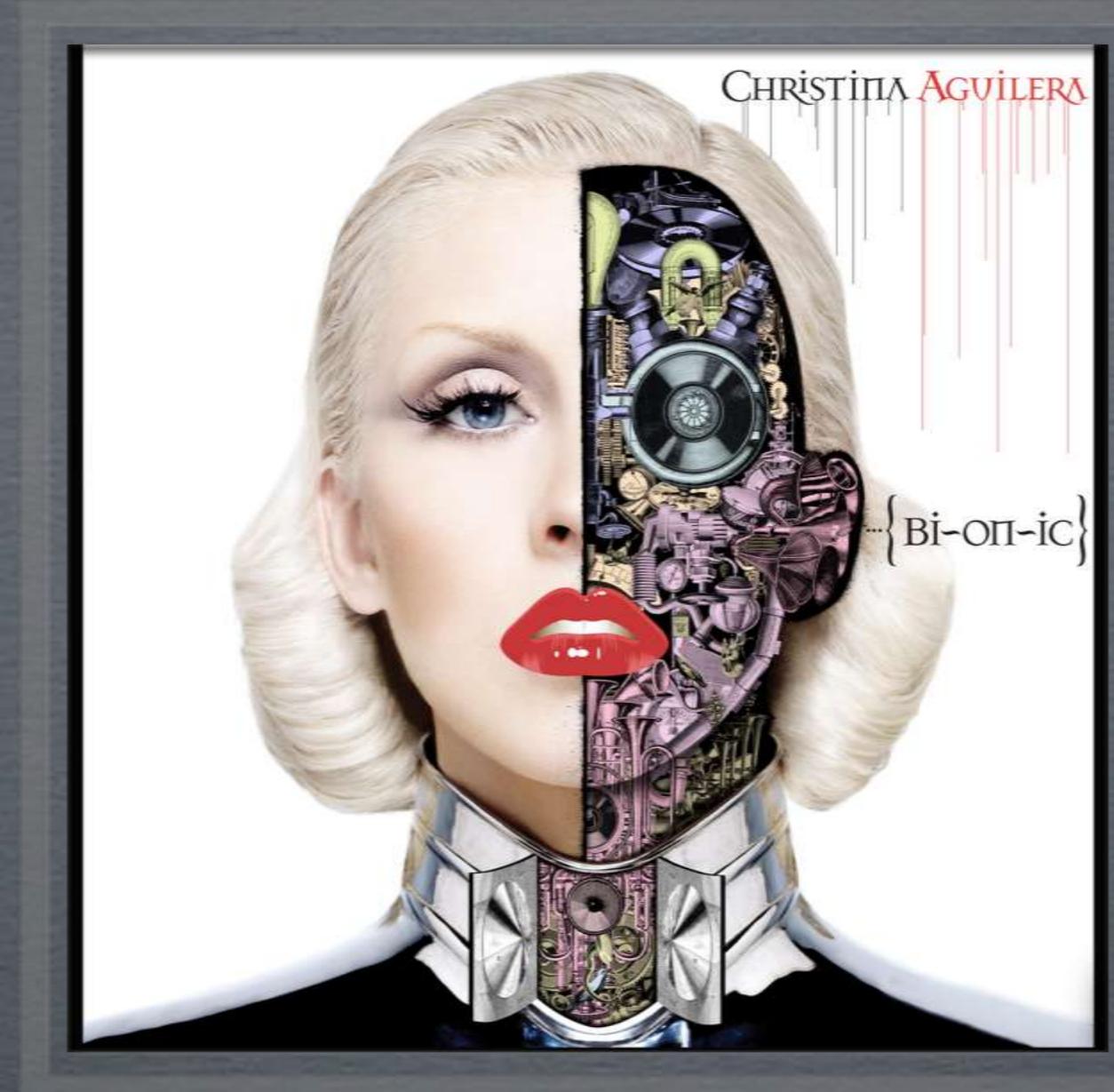




cool



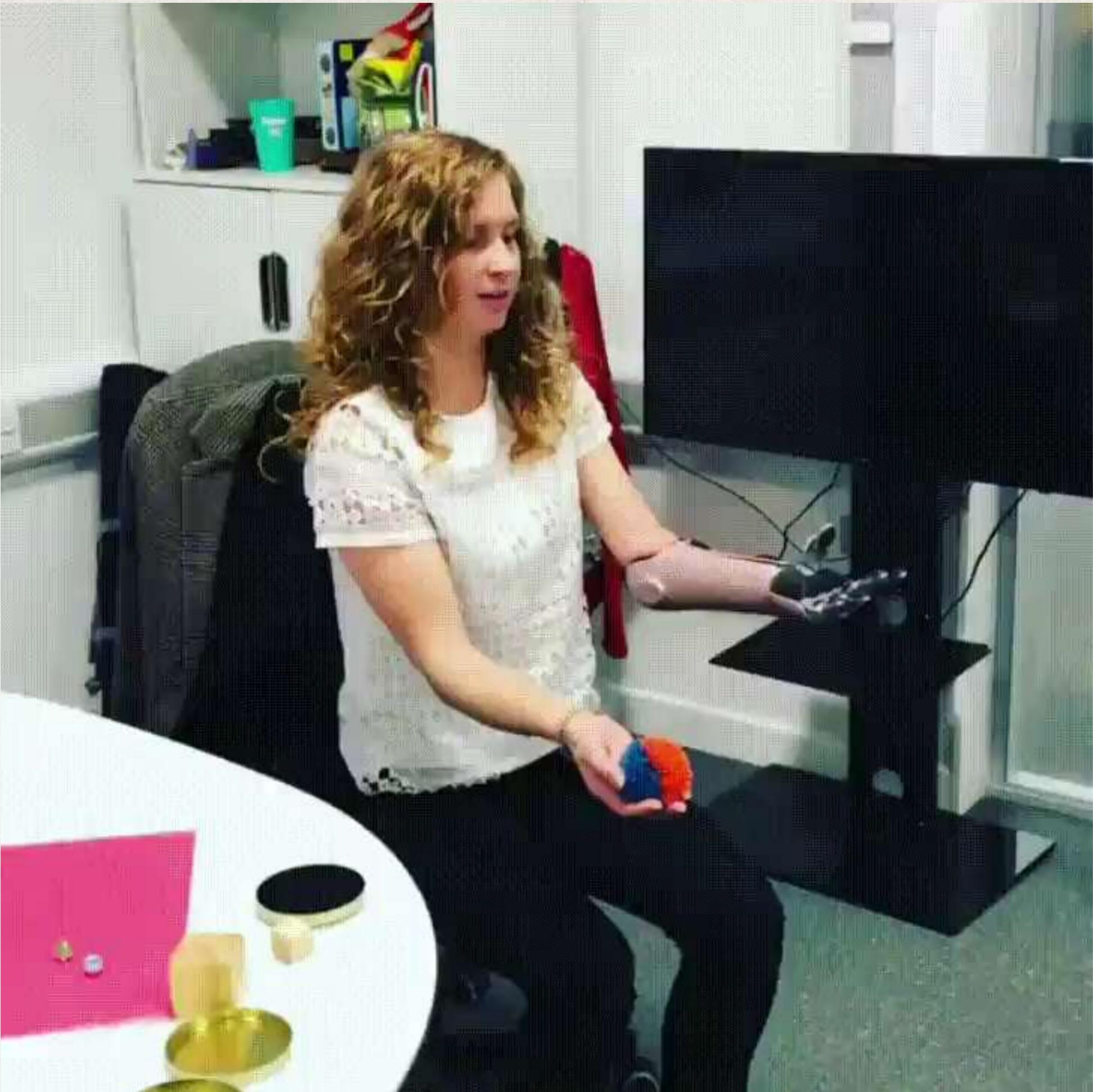
“Cuz I deserve it”



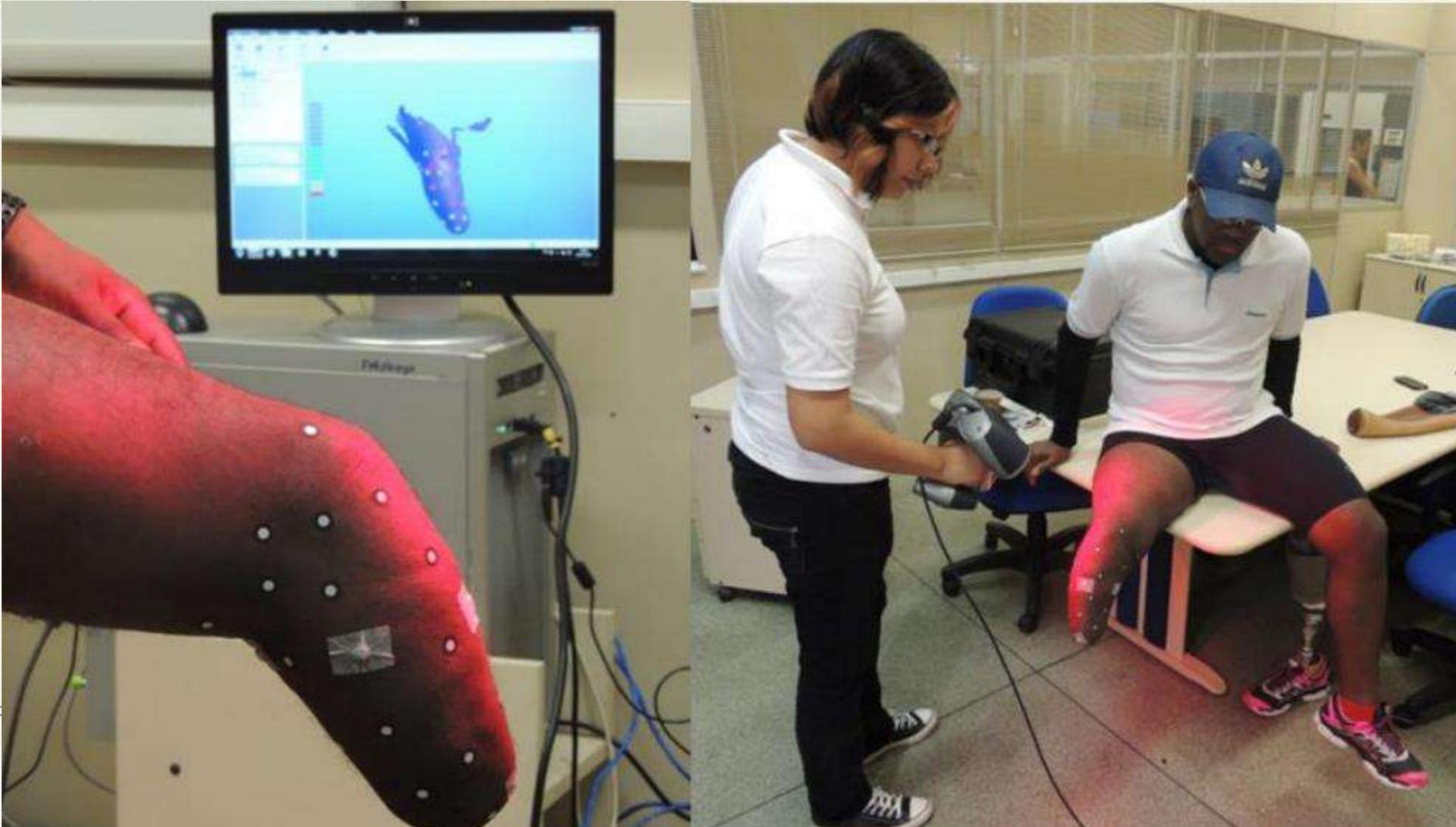
bionic







[Play
video](#)



I give you permission to be
skeptical with your optimism

How do “things” interact with humans?

glasses



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

SECTION THREE:

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

SECTION THREE:

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



How is a prosthesis made?

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.

the celebrated Artificial Limbs, with India
Rubber Hands and Feet.



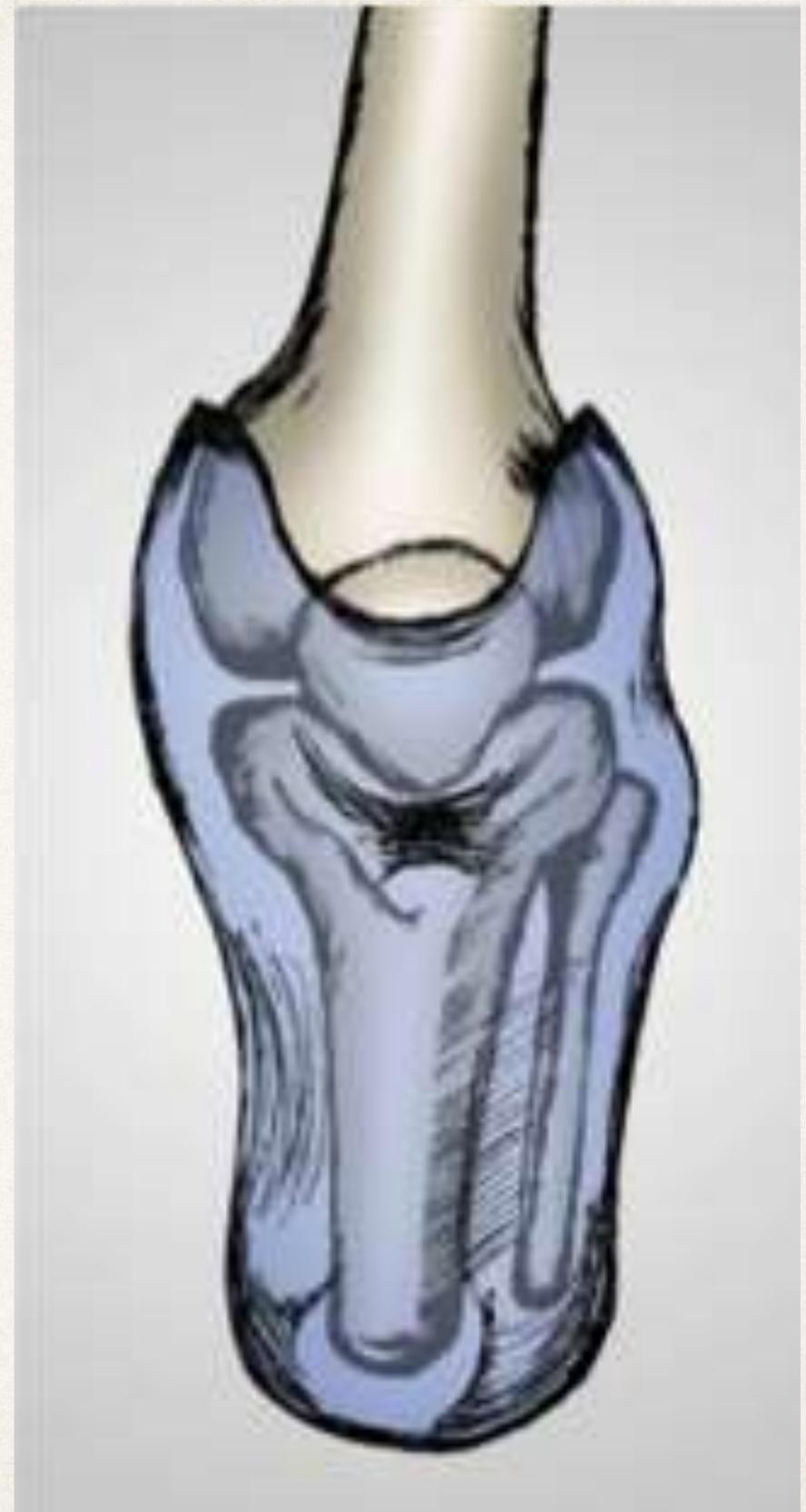
First Premium (GOLD MEDAL,) awarded by the
American Institute, 1865, as the **BEST.**

States Army, to furnish Soldiers with Artificial Limbs, **FREE OF CHARGE.**



CABINET POPULAR
PHOTOGRAPHED BY *Brown* OTTAWA, ILL.

Total Contact / Total Surface Bearing





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??

FDA, ISO, CE and other
regulatory hurdles



The US FDA defines Class 1:

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

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

ISO- International Standards Organization

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

CE Mark

- ❖ 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

PREDICTING CHANGE!





SECTION FIVE:

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







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