

Overview of Lower Limb Prosthetics Research

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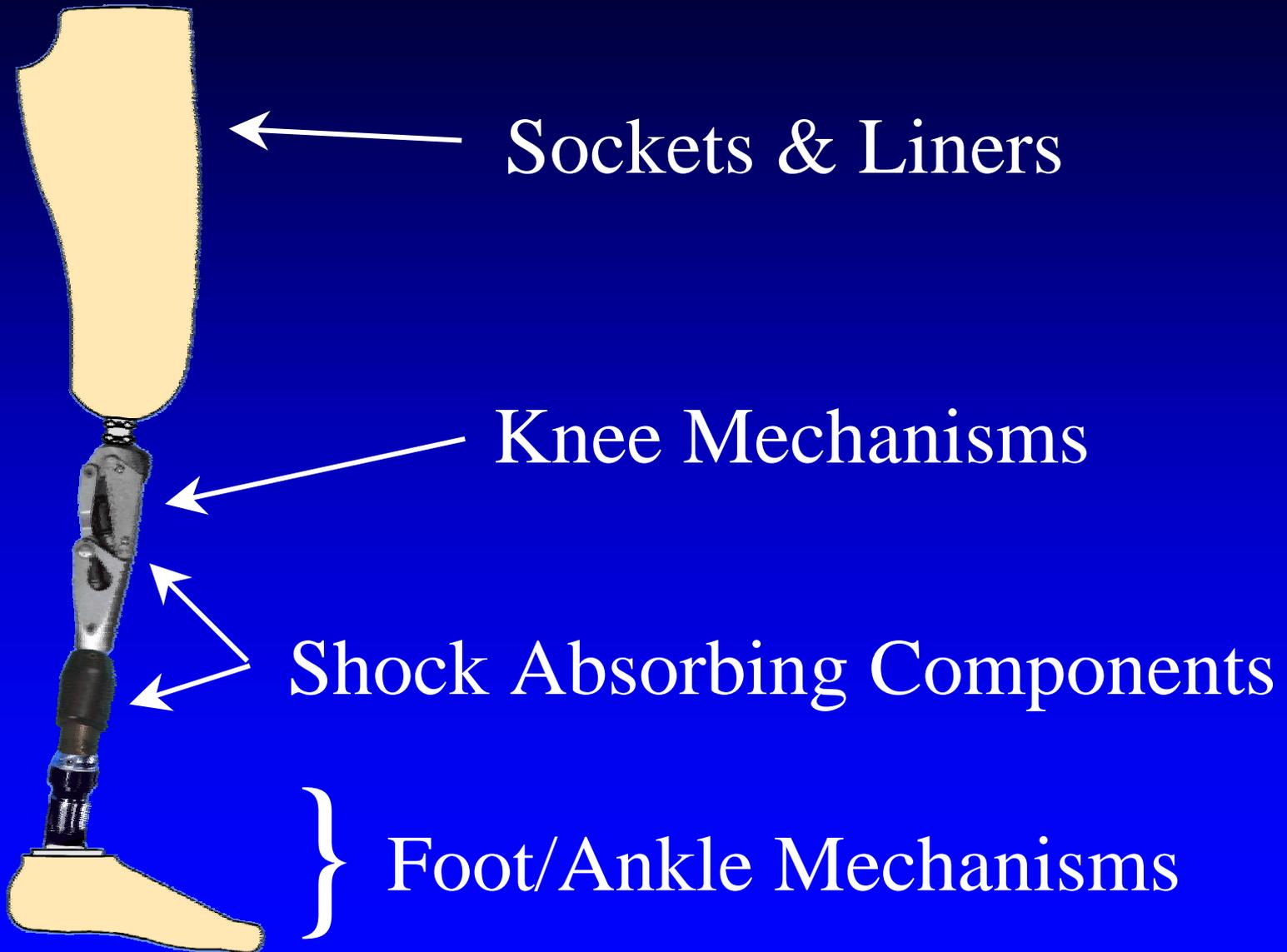
Areas of Investigation in Lower-Extremity Prosthetics

- Amputation surgery/techniques
- Therapy/training
- Identification of clinically useful outcome measures
- Models: simulation, walking, FEA
- Osseo-integration
- Fabrication—Rapid prototyping, CAD/CAM, and materials
- Componentry

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Research Studies of Prostheses



Current Status of Lower Limb Prosthetics Research

- Unsubstantiated claims by manufacturers.
- Small sample sizes; case studies.
- Goals for what we are trying to achieve are ill-defined: What is optimal?

“In much of prosthetics and orthotics, empiricism and pragmatism still dominate. While what prosthetists and orthotists do is rational, they are eager for more science in their art.”

—*John Michael, CPO*

State-of-the-Science Meeting in Prosthetics and Orthotics

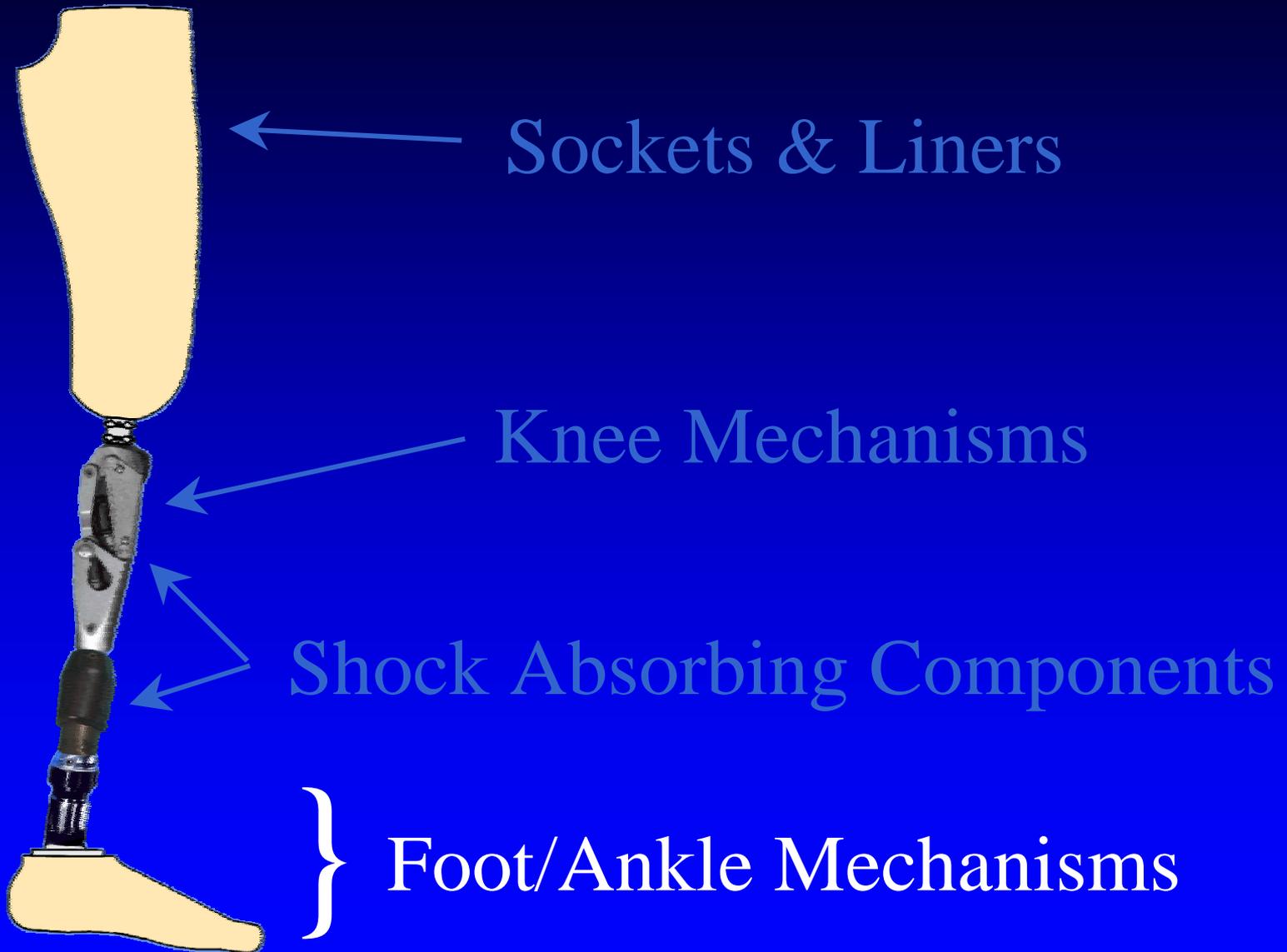
NIDRR RERC in Prosthetics and Orthotics

May 17-18, 2002

Information Prosthetists Need

- Objective evaluations.
- Prescription & Fitting Guidelines.

Research Studies of Prostheses



Prosthetic Foot Designs



College Park Trustep



Otto Bock 1D25



SACH Foot



Ossur Talux



OB Advantage DP2



OB Advantage LP



OWW Carbon Copy HP



Ossur Flexwalk

“The ideal prosthetic foot would imitate perfectly the human foot in form and function. [But] This is not possible given the current technology.”

— Romo (1999)

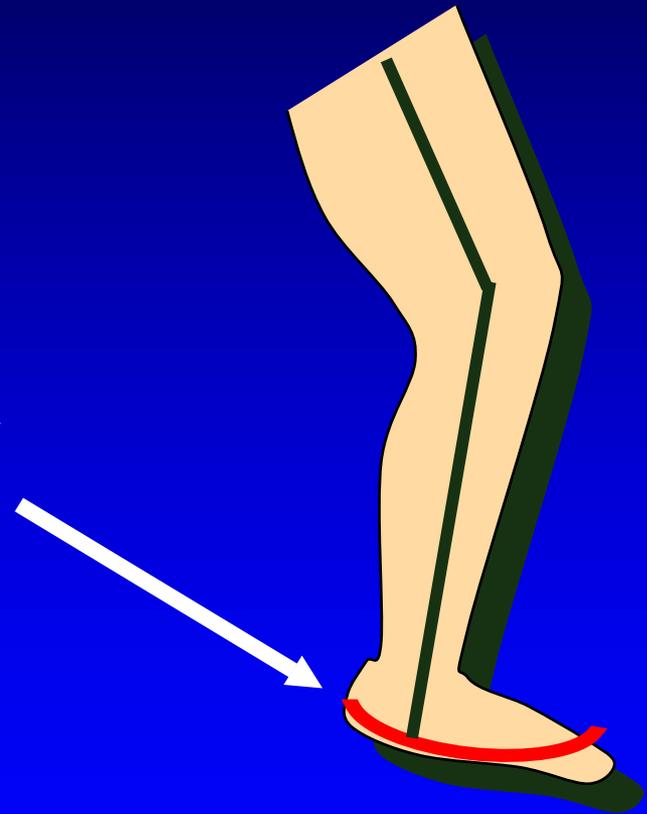
Studies of Prosthetic Feet

Compared with a SACH foot, dynamic response feet:

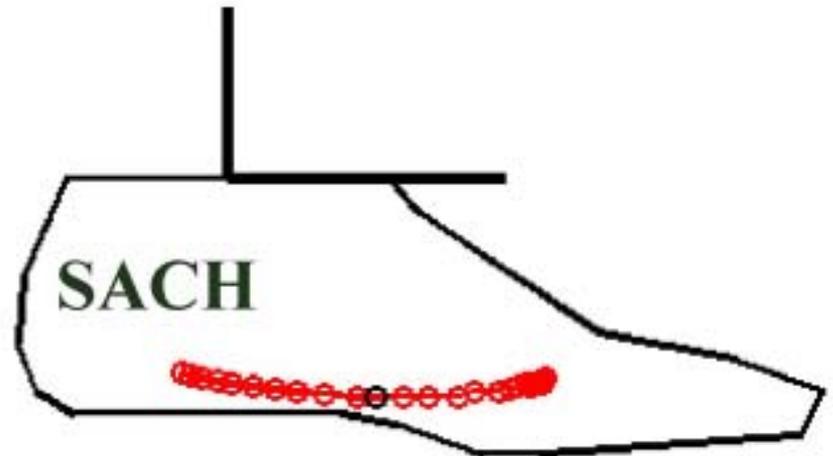
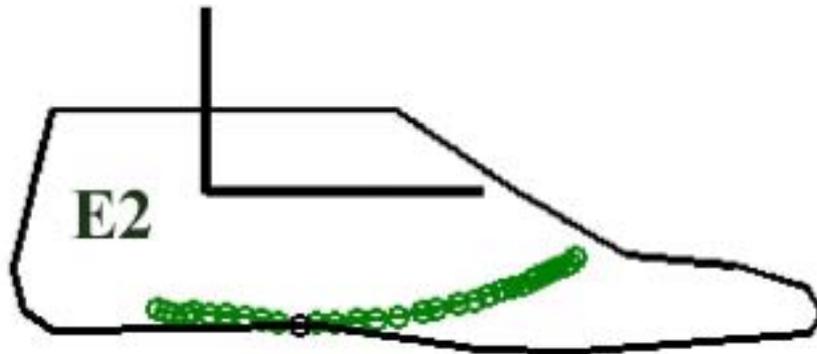
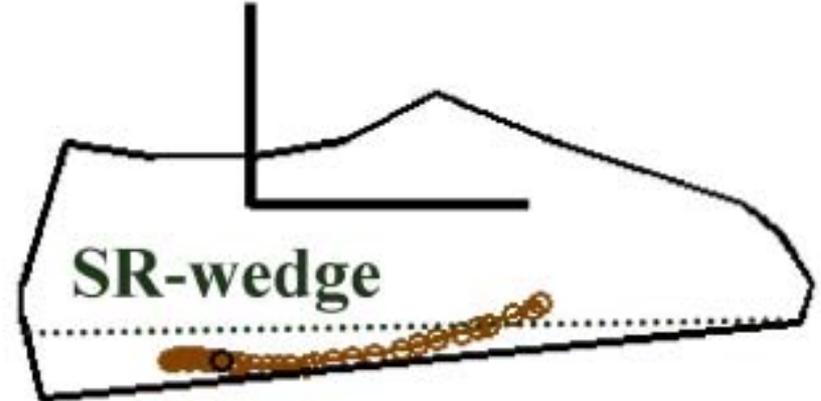
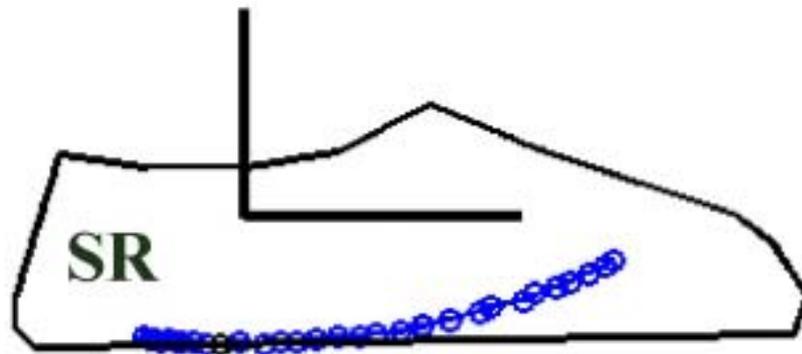
- Have increased range of motion.
(Linden et al., 1999; Rao et al., 1998; Lehmann et al., 1993; Torburn et al., 1994)
- Store and return more energy.
(Gitter et al., 1991; Czerniecki et al., 1991; Postema et al., 1997; Macfarlane et al., 1997)
- Decrease impact loading to sound leg foot.
(Powers et al., 1994)
- May reduce energy required to walk.
(Schneider et al., 1993; Macfarlane et al., 1997)

Studies of Prosthetic Feet

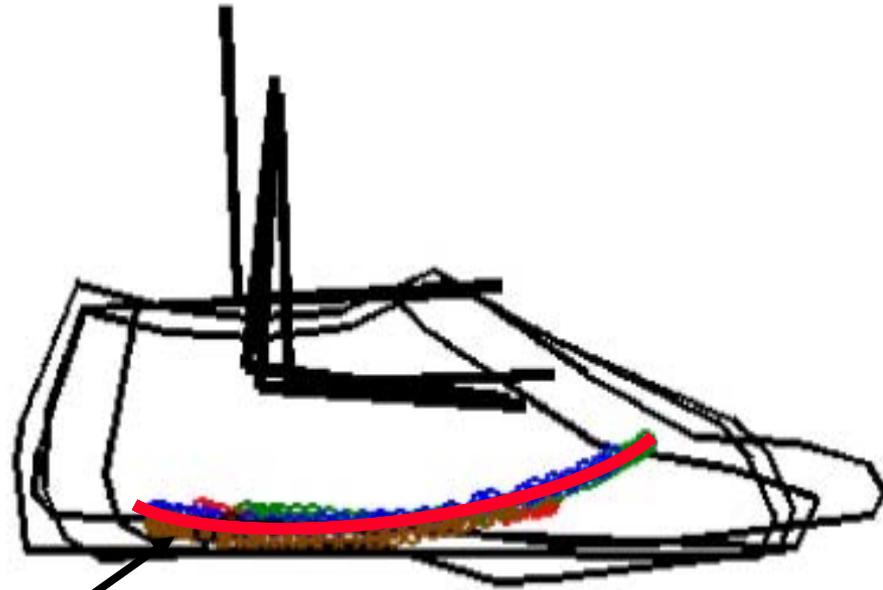
Roll-over shape is the effective geometry (rocker) that the foot/ankle complex conforms to during the stance phase of walking.



Individual Roll-over Shapes



After dynamic alignment by experienced prosthetists...



“Ideal” Shape

Components That Increase Ankle Motion



Endolite Multiflex Foot & Ankle



OWW Earthwalk Ankle



Otto Bock Torsion Adapters



Endolite Torque Absorber

College Park Trustep



College Park Trustep

- Combines virtually the same vertical motion, rotation and stability found in the anatomical foot.

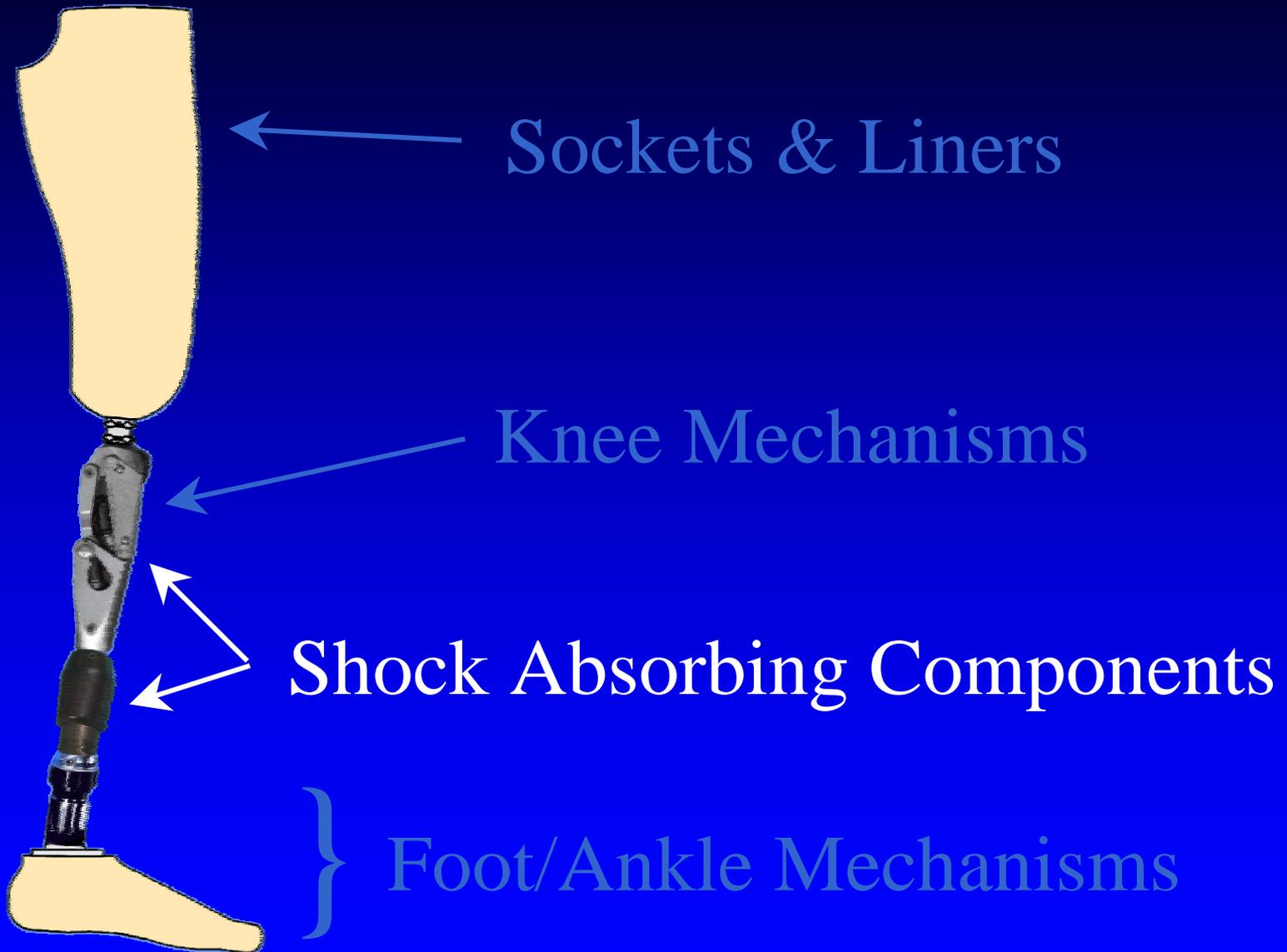
Ohio Willow Wood Earthwalk Ankle



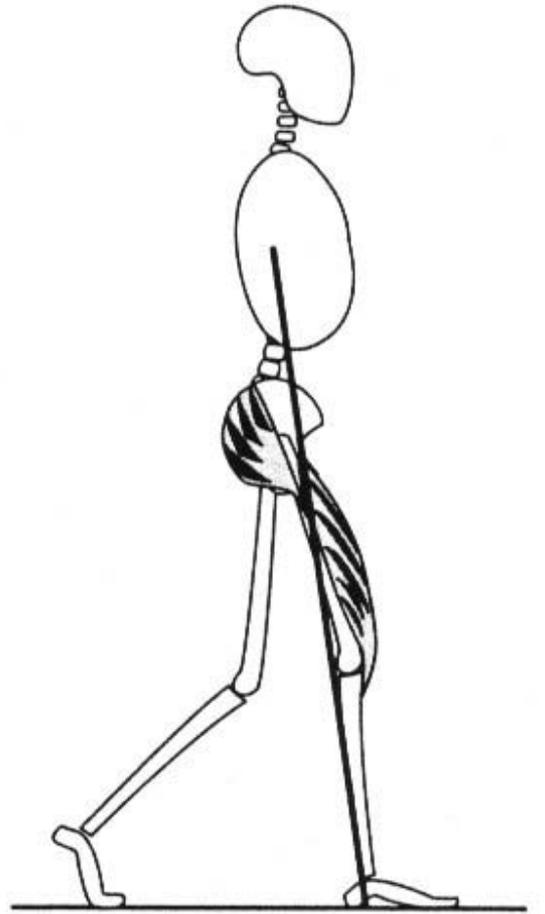
Earthwalk Ankle

- Innovative multi-axial ankle with “lifelike ankle motion.”
- Inversion and eversion, internal and external rotation, and plantar and dorsiflexion.
- Allows for an exceptionally smooth transition from heel strike to toe off.
- Four different ankle stiffness options are available.

Research Studies of Prostheses



Shock Absorption



Loading Response

Perry (1992)

- Abrupt loading of the leading leg during walking necessitates a reduction of shock forces.
- The body appears to utilize strategies to avoid potentially harmful impact shock during gait:
 - Stance-phase knee flexion
 - Pelvic obliquity
 - Reduced walking speed

Shock Absorbing Components



Ossur Ceterus Foot



Ossur Total Shock w/ Feet



Ossur Re-Flex
Vertical Shock Pylon (VSP)



OWW Free-Flow Pylon



Endolite
Mercury TT Pylon



Otto Bock
Delta Twist™ Shock Absorber

Ossur Re-Flex Vertical Shock Pylon (VSP)



Ossur Re-Flex VSP

- First introduced in 1993.
- Provides up to 1 inch (2.5 cm) of vertical compression.
- Nine different compression springs to accommodate range of weights and activity levels.
- Cushions the impact to amputees' residual limbs.
- Stores and return energy to allow the user to walk comfortably, efficiently and naturally.

Endolite Telescopic-Torsion (TT) Pylon



Mercury TT Pylon

- 5-8 mm vertical travel (nominal); 13 mm travel maximum.
- 30 degrees internal and external rotation.
- Three different stiffness springs and torsion rods to accommodate range of weights and activity levels.
- Can be fit with a number of different feet.

Shock-Absorbing Components

Summary of Research Results

- Mooney et al. (1995)
 - Analyzed the gait of a single transtibial amputee using the Re-Flex VSP.
 - Slightly decreased vertical GRF during the loading response phase, and the fore-aft GRF was slightly decreased.
- Miller and Childress (1997)
 - Analyzed the Re-Flex VSP in two transtibial amputee subjects.
 - Few biomechanical differences were found for walking.
 - Reduced GRFs during fast walking and jogging.

Shock-Absorbing Components

Summary of Research Results (cont'd)

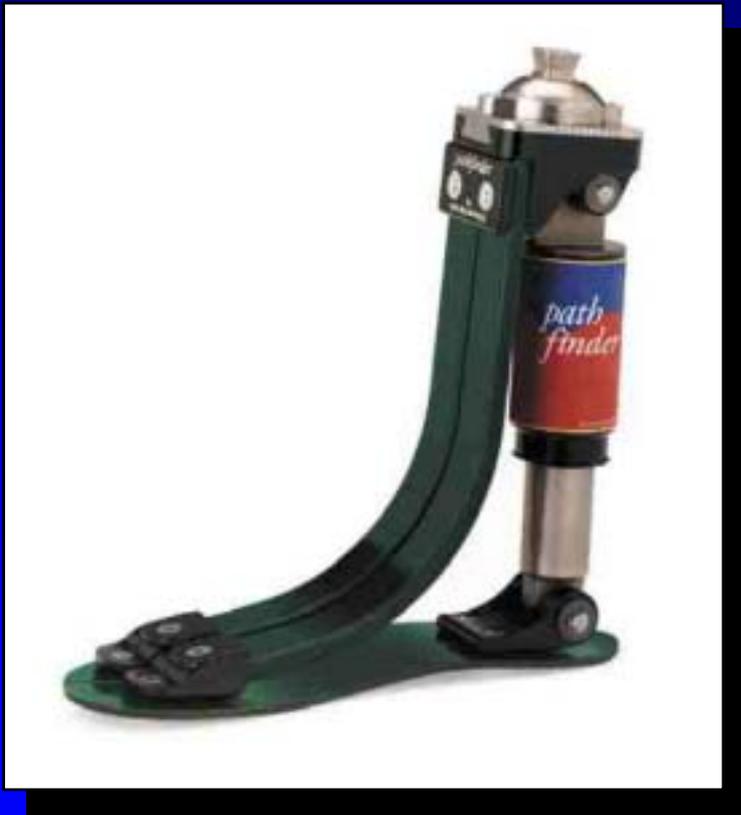
- Hsu et al. (1999)
 - Five men with unilateral transtibial amputations.
 - Re-Flex VSP significantly reduced energy cost, increased gait efficiency, and decreased exercise intensity.
 - Design benefits of the Re-Flex VSP are speed dependent, with the differences become more apparent at speeds above about 1.1 m/sec.
- Buckley et al. (2002)
 - Endolite TT (Telescopic-Torsion) Pylon.
 - Six unilateral transtibial amputees.
 - TT Pylon reduced energy expenditure at speeds 130% and 160% greater than the freely-selected speed. Differences at the speed 160% greater than normal was significant.
 - Four subjects preferred the TT Pylon at all speeds, while two subjects perceived no difference in prosthetic comfort.

Shock-Absorbing Components

Summary of Research Results (cont'd)

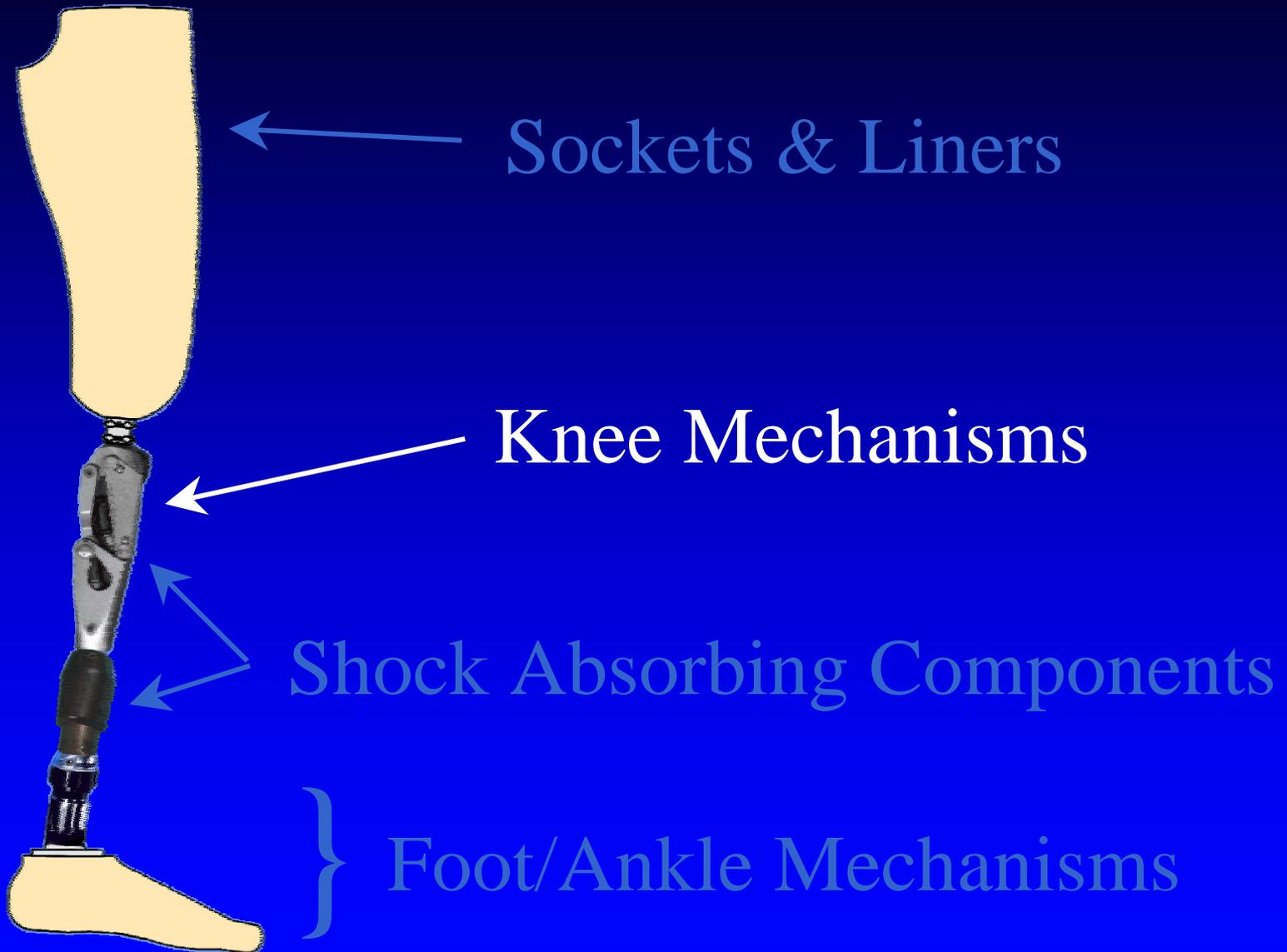
- Gard and Konz (2003)
 - Endolite TT (Telescopic-Torsion) Pylon.
 - Ten subjects with unilateral transtibial amputations.
 - Few quantitative changes in kinematic and kinetic gait parameters
 - Greater step length asymmetry with the TT Pylon than without.
 - Reduction of a force transient associated with impact loading during the prosthetic loading response phase, an effect that was more evident at higher speeds.
 - Subjects generally preferred walking with the SAP for reasons related to comfort.
 - SAPs may provide significant benefit for persons with transtibial amputations who are able to routinely walk at speeds above approximately 1.3 m/sec.

OWW Pathfinder



- Dynamic response, energy-storing foot.
- Pneumatic shock absorber, two composite toe springs, a composite foot plate.
- Provide users with more flexibility, greater dynamic response.

Research Studies of Prostheses



Shock-Absorbing Mechanisms: Stance-Phase Knee Flexion Units



Ossur Total Knee



Otto Bock 3R60 Knee

Stance-Phase Knee Flexion Units

Summary of Research Results

- The ideal prosthetic knee mechanism should absorb shock ... via controlled knee flexion during weight acceptance (Michael, 1994).
- Bouncy Knee (Blatchford)
 - Developed in the late 1970s to restore the stance-phase knee flexion wave observed in normal human walking.
 - Increased gait symmetry, marked improvement in comfort, and increased control in downhill walking (Judge and Fisher, 1981; Fisher and Judge, 1985; Fisher and Lord, 1986).

Stance-Phase Knee Flexion Units

Summary of Research Results (cont'd)

- Blumentritt (1997) evaluated the Otto Bock 3R60 Knee
 - Three transfemoral amputee subjects
 - Subjects reported:
 - ✓ Enhanced feeling of stability,
 - ✓ Relief from having to concentrate on controlling the knee to simply being able to walk confidently.
- Sutherland et al. (1997) evaluated the Ossur Total Knee
 - Case study
 - Significantly increased prosthetic step length, walking speed, and prosthetic stance-phase duration.
 - Remained flexed throughout the prosthetic stance phase.

Microprocessor-Controlled Prosthetic Knees



Endolite IP+



Otto Bock C-Leg

Endolite IP+



- Automatically adjusts hydraulic damping in the knee so the the swing of the prosthesis matches the individual user's walking speeds.
- IP+ wearers comment that they no longer have to think about changes in their walking speeds - the IP+ does it for them.

Otto Bock C-Leg



- Microprocessor-controlled prosthetic knee/shin system with hydraulic damping control during both swing and stance.
- The C-Leg's microprocessor adapts the knee for stairs, slopes, and irregular terrain, allowing the wearer to walk naturally without thinking about it or compensating.

Microprocessor-Controlled Prosthetic Knees

Summary of Research Results

Intelligent Prosthesis (IP) or C-Leg in comparison with conventional, single axis knee joints with pneumatic or hydraulic swing phase control.

(Stinus, 2000; Kirker et al., 1996; Taylor et al., 1996; Buckley et al., 1997; Heller et al., 2000; Schmalz et al., 2001; Chin et al., 2003; Meier et al., 2003)

- User perception

- Generally in favor of IP or C-leg. Easier to walk on inclines, stairs, at different speeds and for longer distances.

(Stinus, 2000; Kirker et al., 1996; Taylor et al., 1996; Datta and Howitt, 1998)

- Oxygen consumption

- C-leg: Decrease in 4 out of 6 participants, increase in 2 participants.

(Schmalz et al., 2001)

- IP: Reduction at slow and fast speeds; No change at normal speed.

(Taylor et al., 1996; Buckley et al., 1997)

- Walking speed

- IP: Participants were able to walk at faster speeds with relative reduction in energy expenditure. (Chin et al., 2003)

Microprocessor-Controlled Prosthetic Knees

Summary of Research Results (cont'd)

- Cognitive demand
 - Heller et al. (2000)
 - Ten unilateral transfemoral amputee subjects
 - IP vs conventional pneumatic swing-phase control
 - Subjects walked on treadmill at varying speeds while performing cognitively distracting task.
 - Walking with IP was not found to be less cognitively demanding.
 - Meier et al. (2003)
 - Three unilateral transfemoral amputee subjects
 - C-Leg vs Otto Bock 3R60 Knee (hydraulic swing-phase control)
 - Walking on level and through obstacle course while performing mental loading task
 - C-Leg tends to facilitate fast level walking speeds, especially under a mental loading task.
 - Issues with C-Leg on compliant surfaces and walking down ramps.

Endolite Adaptive Knee



- Introduced in late 2002
- “The first microprocessor-controlled knee that combines the power and stability of hydraulics with the natural comfort of pneumatics ...”
- Walk at fast or slow speeds
- Negotiate stairs or ramps
- Allows the amputee to wear any existing prosthetic foot.

Endolite Adaptive Knee

Prolite Smart Magnetix Knee

Biedermann Motech



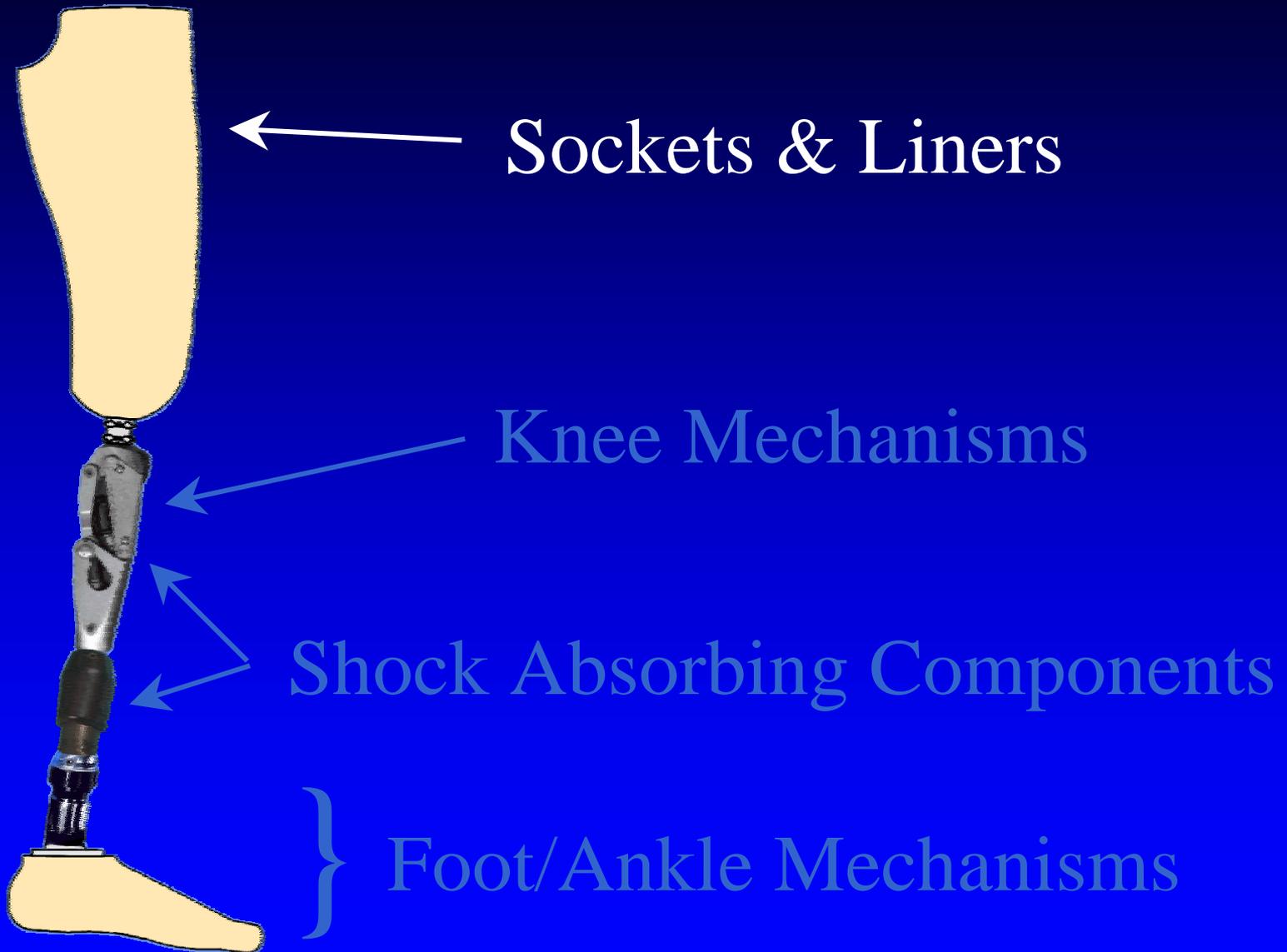
- Utilizes Rheonetic™ MR fluid dampers from the Lord Corp.
- Improves mobility; makes climbing up and down stairs and inclines much easier.
- Increases gait balance, stability and energy efficiency.
- A fraction of the cost of other high-end knee products.
- Less costly, less complex and more dependable than state-of-the-art, motor-controlled, active damper systems.

Teh Lin “Auto-Pilot” Electric Intelligent Knee



- Fuzzy logic control—No need to adjust. It instantly and constantly learns and adjusts to all patient's gait requirements.
- Precisely adjusts the flexion and the extension of the knee with the speed of gait.
- Positive stance flexion stability.
- Quiet, smoothest pneumatic true variable cadence.

Research Studies of Prostheses



Transfemoral Prosthetic Socket Design

No other prosthetic component is as crucial in assuring a comfortable and well-functioning prosthesis as the socket (Kapp, 2000).

Socket fit rated as the most important issue among users of lower-limb prostheses (Legro et al., 1999).

Transfemoral Prosthetic Socket Design

Quadrilateral Socket

- Introduced in the 1950s.
- Four-sided shape of the socket when viewed transversely.
- Strong emphasis on individual anatomy of soft tissues and underlying bony structures.
- Direct ischial bearing on a brim or shelf.

Ischial Containment Socket

- Introduced in the 1980s.
- Narrower in the M-L dimension to gain better control of femur and maintain its normal alignment.
- Ischium contained within socket using bony lock.
- Goals include increased comfort for user, and improved control of pelvis and trunk.

Although both are widely used, there is limited objective analysis available about the effects of either socket design on transfemoral amputee gait.

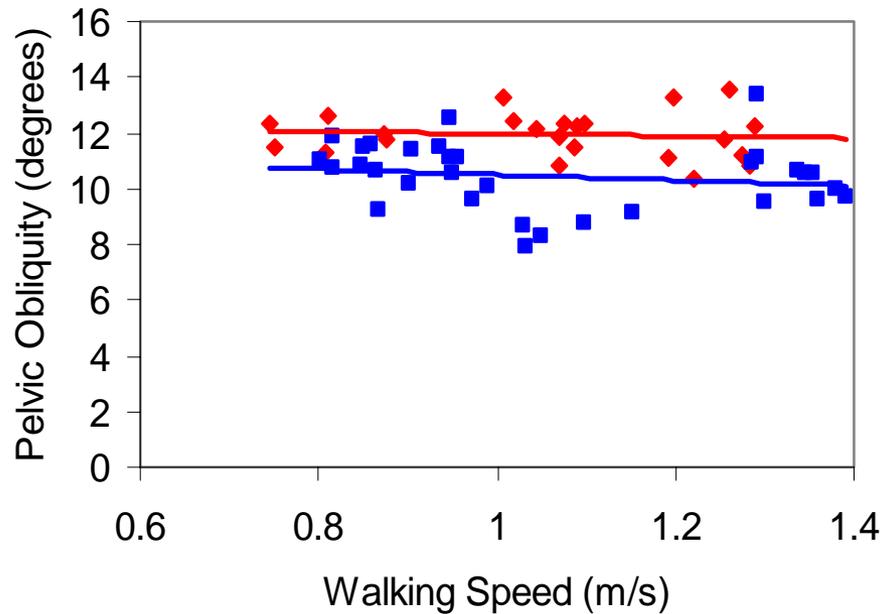
Prosthetic Sockets

Summary of Research Results

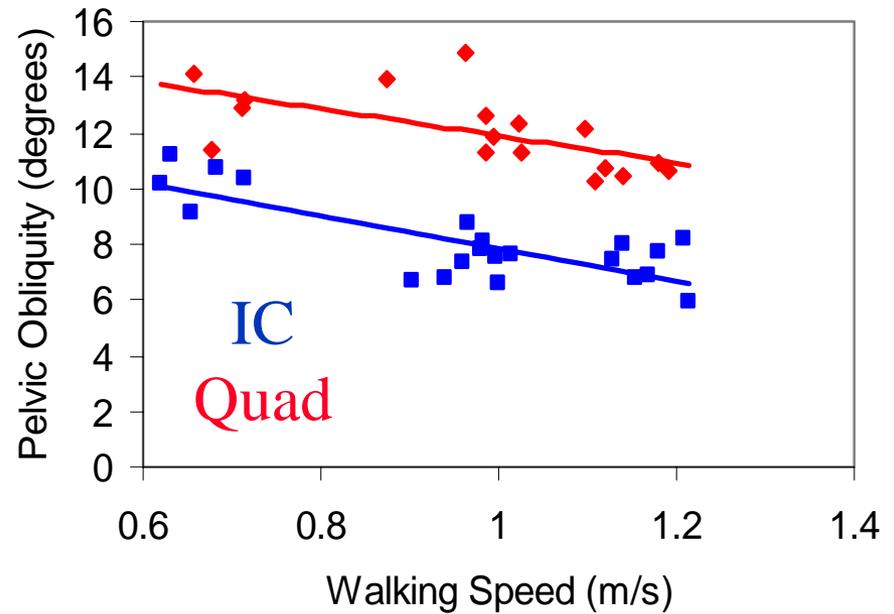
- Gailey et al. (1993) reported that while ambulating at their normal pace, non-vascular transfemoral amputees used 20% less energy when wearing a IC socket than a Quad socket.
- Hall et al. (1995) reported that the IC socket may reduce base width, side-sway, and pressure over the ischial tuberosity, and increase the freely-selected speed of walking when compared to the Quad socket.
- Flandry et al. (1989) reported that the IC socket improved adduction of the residual limb, stride length, velocity, energy expenditure and decreased lateral trunk lean.

NUPRL Transfemoral Socket Study

Pelvic Obliquity vs Walking Speed



Subject 1



Subject 2

Socket Liners

(Gel & Silicone)



Alps EASYLINER Locking Liner

“The single most critical aspect of any prosthesis is the quality of the interface between the residual limb and the prosthesis.” Marks & Michael (2001)



OWW Original Alpha Liner



Otto Bock Silicone Liners

Gel & Silicone Socket Liners

Summary of Research Results

- Reduce average and peak pressures on the residual limb.
Sonck et al. (1970)
- Improve the weight-bearing capability between the prosthesis and user.
Kristinsson (1993)
- Reduce rate of skin breakdown.
Datta et al. (1996), Cluitmans et al. (1994)
- Improve comfort & improve suspension (w/ pinlock system)
Hatfield and Morrison (2001), Narita et al. (1997)

TEC Harmony System— Vacuum Assisted Socket System (VASS)



- System consists of a TEC liner, suspension sleeve and air evacuation pump.
- Creates an elevated vacuum between the liner and the socket wall
- Increases suspension and proprioception.
- Reduces volume fluctuation in the residual limb.
- Increases comfort and avoids the inconvenience of the user having to add or remove socks to maintain the fit of his or her prosthesis.

“Civilians get crappy legs, but ours [are] going to be top of the line.” —*Quote from returning soldier who sustained a transfemoral amputation.*

[Thompson, M. “The Wounded Come Home,” *Time*, Nov. 10, 2003.]

“There is often a tendency to fit a more expensive device, whether or not the amputee can use it effectively. This is due to many factors, one being the amputee who ‘wants the best’ and believes the best must obviously be the most expensive.”

—*Charles Radcliffe, MS, ME*

Professor of Mechanical Engineering (Emeritus)

University of California at Berkeley

[Otto, J. “Prosthetic Knees: What’s on the Way?” *The O&P Edge*, 2(10), 22-28, Oct. 2003]

“The most advanced application of technology is not necessarily the same as the application of the most advanced technology.”

—*Fred Forchheimer*

Swedish Rehabilitation Engineer