ÖSSUR ACADEMY

Optimising Outcomes: Subischial Socket design with Unity, Pro-Flex® Family, updated RHEO KNEE XC® Features, and Mechanical Knee considerations

AOPA 2017 –Technical and Training workshop

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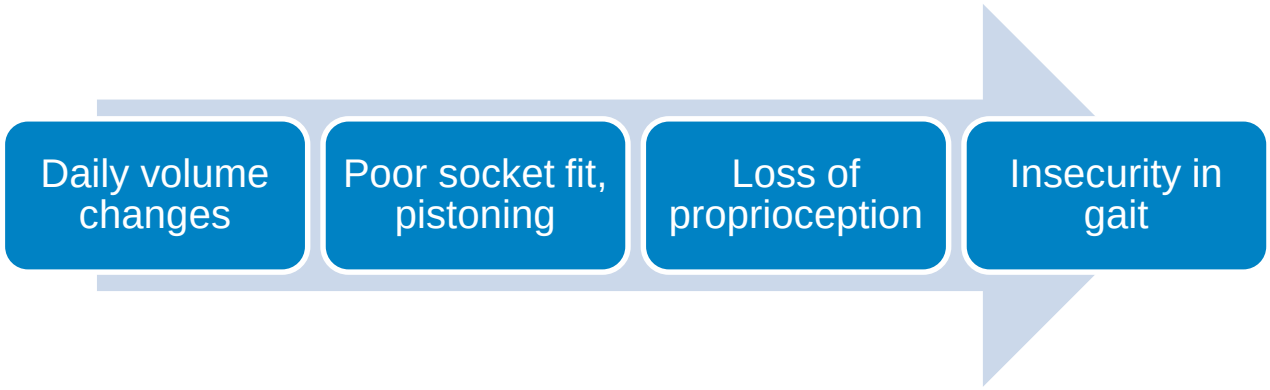
Optimising Outcomes Workshop

- **Subischial Socket design**
  - Unity Elevated Vacuum
  - Subischial Socket design
  - Casting method
  - Training considerations
- **Updated Pro-Flex Family products**
- **RHEO KNEE Update**
  - Updated functions of the RHEO KNEE
  - How to Programme
  - Training considerations
- **Mechanical Knee Considerations**
  - Overview of mechanical knee range
  - Introducing the PASO Knee
  - Training considerations
  - Learning to Run

Unity Elevated Vacuum: Advantages of vacuum suspension

- **Very firm suspension** providing excellent security and improved **proprioception**
- Elevated vacuum tends to assist in maintaining more **constant limb volume**, thereby decreasing the need to add additional socks
- Elevated vacuum **assists with wound healing** by improving circulation through the residual limb
- Provides good distal comfort for bony and sensitive distal ends; as long as the socket fits properly with good **volume and length matching**

Medical Necessity: Active Vacuum



Conclusion: Control of volume is a necessity[1]

[1]Board et al. (2001) J Int Prosth & Orth.

Medical Necessity: Active vacuum

Evidence regarding increased safety:

- Activities-specific Balance Confidence scales (ABC test) were found to be significantly higher in participants using vacuum suspension with 95% confidence, indicating a lower predicted incidence of future falls
- Improved functional outcome[2]: 'skin problems (breakdown and blistering) seemed to be decreased in vacuum users and walking times increased in some users'

[2]Ferraro, C. Outcomes study of transtibial amputees using elevated vacuum suspension in comparison with pin suspension. J. Prosthet. Orthot. 23(2):78–81; 2011.

The Activities-specific Balance Confidence (ABC) Scale*

For each of the following activities, please indicate your level of self-confidence by choosing a corresponding number from the following rating scale:

0% 10 20 30 40 50 60 70 80 90 100%
no confidence completely confident

"How confident are you that you will not lose your balance or become unsteady when you…

1. …walk around the house? ____%
2. …walk up or down stairs? ____%
3. …bend over and pick up a slipper from the front of a closet floor ____%
4. …reach for a small can off a shelf at eye level? ____%
5. …stand on your tiptoes and reach for something above your head? ____%
6. …stand on a chair and reach for something? ____%
7. …sweep the floor? ____%
8. …walk outside the house to a car parked in the driveway? ____%
9. …get into or out of a car? ____%
10. …walk across a parking lot to the mall? ____%
11. …walk up or down a ramp? ____%
12. …walk in a crowded mall where people rapidly walk past you? ____%
13. …are bumped into by people as you walk through the mall?____%
14. … step onto or off an escalator while you are holding onto a railing? ____%
15. … step onto or off an escalator while holding onto parcels such that you cannot hold onto the railing? ____%
16. …walk outside on icy sidewalks? ____%

*Powell, LE & Myers AM. The Activities-specific Balance Confidence (ABC) Scale. *J Gerontol Med Sci* 1995; 50(1): M28-34

Medical Necessity: Active vacuum

ÖSSUR ACADEMY

Evidence regarding volume control:

- The vacuum-assisted socket has been shown to eliminate daily volume loss[3]
- Vacuum-assist ensures a good fit during the day in ambulatory trans-tibial traumatic amputees with mature stumps[4]
- The combination of reduced pistoning and maintenance of volume is thought to account for the more symmetrical gait observed with vacuum[1]
- Elevated vacuum suspension systems manage limb volume fluctuation, a problem that people with limb loss are challenged with[5]

[3]Beil, T. L.; Street, G. M.; Covey, S. J. Interface pressure during ambulation using suction and vacuum-assisted prosthetic sockets. J. Rehabil. Res. Dev. 39(6):693–700; 2002.

[4]Goswami, J.; Lynn, R.; Street, G.; Harlander, M. Walking in a vacuum-assisted socket shifts the stump fluid balance. Prosthet. Orthot. Int. 27(2):107–113; 2003.

[1]Board, W. J.; Street, G. M.; Caspers, C. A comparison of trans-tibial amputee suction and vacuum socket conditions. Prosthet. Orthot. Int. 25(3):202–209; 2001.

[5]Sanders, Joan E., et al. Effects of elevated vacuum on in-socket residual limb fluid volume: case study results using bioimpedance analysis. Journal of Rehabilitation Research & Development, 2011, 48. Jg., Nr. 10.

Medical Necessity: Active vacuum

Evidence addressing fit, comfort and limb health:

- When limb volume decreases, the socket is loose-fitting, often causing pressure to bony prominences, which may result in pain and/or injury to the limb[1].

[5]Sanders, Joan E., et al. Effects of elevated vacuum on in-socket residual limb fluid volume: case study results using bioimpedance analysis. Journal of Rehabilitation Research & Development, 2011, 48. Jg., Nr. 10.

Primary benefits of the Unity™ system

Unity™

- **SLEEVELESS:** Increased knee flexion range (TT) with greater comfort and user acceptance
- **LIGHT WEIGHT AND DISCREET:** 130g added weight and housed within foot shell
- **SIMPLE AND EFFICIENT:** Quick and easy to elevate and release vacuum levels
- **INDEPENDENT PUMP:** does not depend on shock mechanisms and can be added to a wide range of performance Flex-Foot systems to meet every mobility need.
- **VOLUME STABILISATION:** Optimizes socket stability, proprioception and comfort throughout the day while limiting the need to add socks
- **INCREASED RELIABILITY:** Minimizes risk of leaks and puncture issues associated with sleeve dependent vacuum methods
- Integrates **PERFORMANCE FLEX-FOOT** technology to meet all activity requirements

Unity: Candidate Profiling

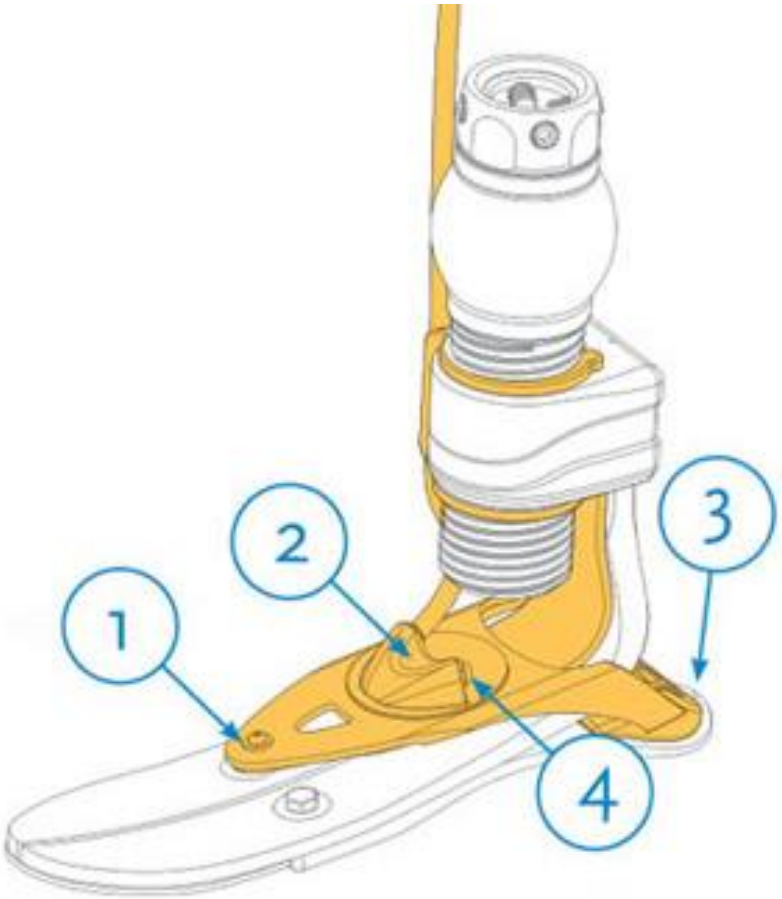
Indicated user population:

- Transtibial and Transfemoral amputees
- Low to high impact levels
- Weight limit entirely based on recommended foot and knee modules
- Sufficient residual limb length to use Seal-in V and Seal in X liners
- Very conical limbs may be addressed using a distal cup

Contraindications for use:

- When total contact cannot be maintained distally between liner and limb
- When expecting significant volume changes

Integrated Unity™ Pump & Flex-Foot



1. Frame & Support Blade:
Upon heel deflection, the frame moves up and the support blade moves down, thus expanding the membrane.

2. Check valves:
When air is efficiently drawn out of the socket, check valves ensure that air does not flow back into the socket **(Pre-assembled for L side).**

3. Heel pad:
The heel pad acts as a secure support for Unity's upper blade, and as a stop for heel displacement at high load.

4. Membrane:
When the membrane deflects, air is efficiently drawn out of the socket.

Complete Flex-Foot solutions with Unity

*Not including Talux or Sport Solutions

Unity Knee solutions for K1-K3

+

Depending on user needs, activity level and impact level choose the suitable knee system
The Ossur range features knees with weight activated breaking mechanism, polycentric 4 bar knees and pneumatic cylinders for users capable of varied cadence

Unity Knee solutions for K3-K4

Depending on user needs, activity level and impact level choose the suitable knee system
The PASO features an autoadaptive pneumatic cylinder, capable of walking speeds of 7km/hr +
The Rheo Knee XC is weatherproof, featuring stair ascent capability, automatic cycling recognition and running

Subischial Socket design: Nu-FlexSIV

- Ryan Caldwell and Stephania Fatone have worked with Northwestern University, and have developed a teachable technique for flexible subischial vacuum sockets:
  - **Northwestern University Flexible Sub Ischial Vacuum Socket** (NU-FlexSIV Socket)
- Ryan Caldwell has been fitting NU-FlexSIV sockets for over 10 years and to 125+ amputees
- The main aim of the subischial socket is to **provide comfort** for the user **without limiting function**
- NU-FlexSIV trim lines typically sit **25mm below the ischial tuberosity** and **50mm below the greater trochanter:**
  - Global compression of soft tissue to relieve pressure on the distal femur
  - User benefits from increased ROM as socket wall no longer limits movement
  - Utilises TT liners which are undersized 10-30% depending on tissue consistency
  - Definitive socket consists of flexible inner socket and carbon fibre outer socket
  - Research has shown that elevated vacuum increases socket comfort with the Nu-FlexSIV

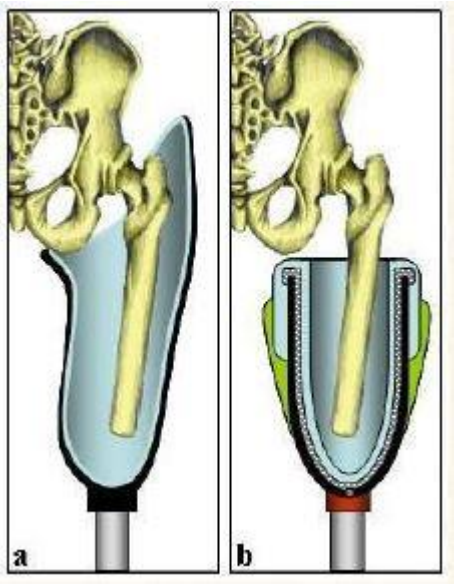
[6]Prosthetics and Orthotics International: Northwestern University Flexible Subischial Vacuum Socket for persons with transfemoral amputation-Part 1: Description of technique. Stefania Fatone and Ryan Caldwell

7Prosthetics and Orthotics International: Northwestern University Flexible Subischial Vacuum Socket for persons with transfemoral amputation: Part 2 Description and Preliminary evaluation. Stefania Fatone and Ryan Caldwell

Ischial Containment vs Nu-FlexSIV

Ischial Containment

The most proximal aspect of the socket includes ischial ramal containment and trim lines proximal to the ischial tuberosity



Nu-FlexSIV

Trim lines typically 25mm distal to the ischial tuberosity and do not impinge on the pelvis

Lower proximal trim lines

Flexible socket construction

Vacuum assisted suspension

Improve comfort and function

8Development of the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket for Persons with Transfemoral Amputation
Ryan Caldwell, CP/L FAAOP, and Stefania Fatone, PhD, BPO(Hons), Northwestern University Prosthetics-Orthotics Center (NUPOC)

Candidate profiling

Indicated user population:

- Fatone and Caldwell suggest that the Nu-Flex-SIV method is best suited for experienced, compliant amputees with residual limbs that are well healed with well-regulated volume
- Caldwell however has over 10 years of clinical experience with technique, successfully fitting more complex limbs with open wounds, scarring, invaginations, heterotrophic ossification, bone spurs, and skin grafts, suggesting that with experience, broader application may be possible.

Contraindications for use:

- stump length < 12cm
- deep longitudinal invaginations
- significant muscle bunching
- issues with silicone liners

[6]Prosthetics and Orthotics International: Northwestern University Flexible Subischial Vacuum Socket for persons with transfemoral amputation-Part 1: Description of technique. Stefania Fatone and Ryan Caldwell

Liner Selection

- TT liners are used to compress the limb to create a generic cylindrical shape, stiffening the soft tissues to achieve stability of the socket with respect to the residual limb
- Heavily scarred or bulbous residual limbs can be addressed with a custom liner to ensure total contact
- Most limbs can be fit with an off-the-shelf TT liner
- TT liners are preferred as their non tapered, cylindrical profile provides a relatively high compression of the softer proximal tissues
- Recommend **downsizing the liner from 10%-30%** ensuring compression and total contact distally
- Liners which incorporate fabric are on the exterior surface are preferred, to wick air from between the liner and socket to maintain suction

[6]Prosthetics and Orthotics International: Northwestern University Flexible Subischial Vacuum Socket for persons with transfemoral amputation-Part 1: Description of technique. Stefania Fatone and Ryan Caldwell

Recommended Liners

- **Relax 3C Cushion:** Users with soft tissue
- **Synergy Cushion:** Users with firm tissue
- **Seal-in X TF:** Sport applications and when using a sleeve is not preferred

[6]Prosthetics and Orthotics International: Northwestern University Flexible Subischial Vacuum Socket for persons with transfemoral amputation-Part 1: Description of technique. Stefania Fatone and Ryan Caldwell

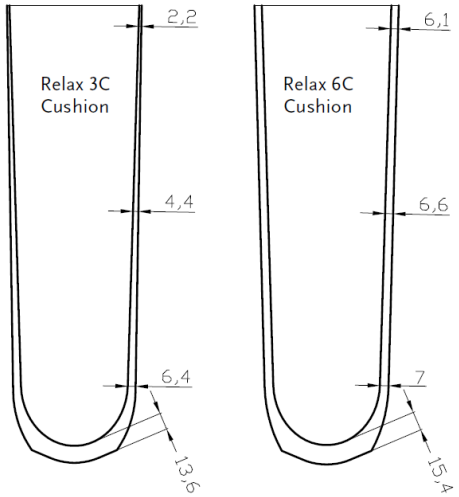
Relax 3C Cushion

Silicone liner with a unique Umbrellan textile cover for phantom pain relief

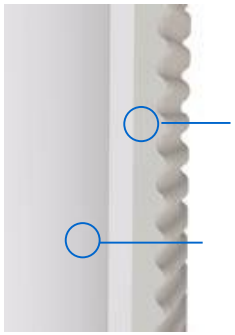
User profile:

- Transtibial amputation
- Phantom pain, phantom sensations, idiopathic residual limb pain
- All K-levels
- 3 mm (3C) and 6 mm (6C)

The innovative Umbrellan knit – woven into the RELAX products – has a shielding action against electromagnetic influences and can help reduce, or even abolish, phantom pain and sensations – there are no known side effects for this. The efficacy has been proved by a scientific study and recognised by the allocation of a medical aid number by the central association of the German statutory health funds.

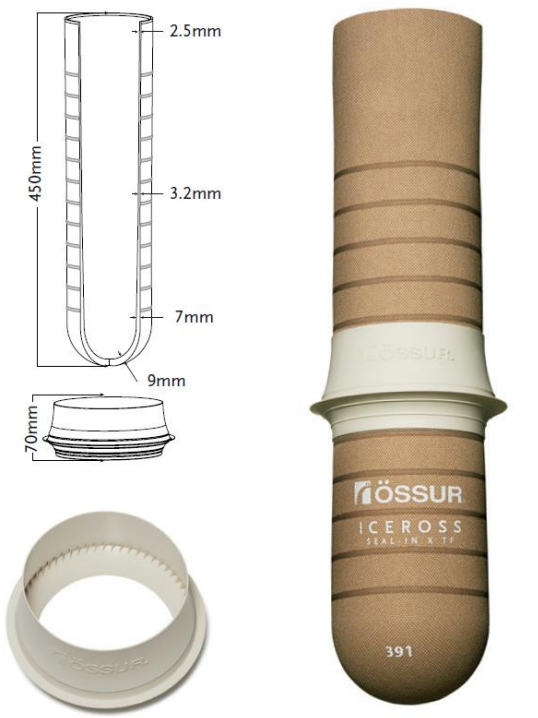


Iceross® Synergy Cushion



- Standard 3mm profile
- Soft & firm silicone layers offer soft tissue stability, cushioning and impact protection
- Outer layer Silicon- DermoSil® Firm durometer
- Inner layer Silicon- DermoGel® Softest durometer
- Active Skin Care:
  - Aloe Vera
  - Vaseline
  - Menthol
- Available only with cover:
  - Sizes 16-45 cm
- Matrix options:
  - 10cm
  - Custom (2-14cm)
  - Warranty: 9 months

Iceross® Seal-In® X TF



- Use without Seal Rings for Nu-FlexSIV sockets
- Standard and Conical profiles
- Slightly stiffer to give better stability and support to proximal tissues
- Thinner distal thickness (9mm) for easier donning and better conformance to limb shapes
- Liner length 5cm longer- benefit long TF and KD users
- New textile cover with 2X adhesion strength and abrasion resistance compared to existing range

Seal-Ring Sizing

- Decide preferred Seal-Ring placement on the limb
- Recommend placement at least 10-15cm below perineum
- Take a circumference measurement directly over the limb where the **lower edge** of the Seal-Ring is expected to rest
- Choose the closest Seal-Ring size to the measurement. If between sizes, choose the smaller size.
- **Conical or "fleshy" limbs may require downsizing one ring size**

RIGHT

TIGHT

When test fitting a liner with a selection of Seal-Rings, observe tension of ring on limb and interface.

Seal-Ring should flatten out on liner without deforming the limb shape.

Determining tissue consistency

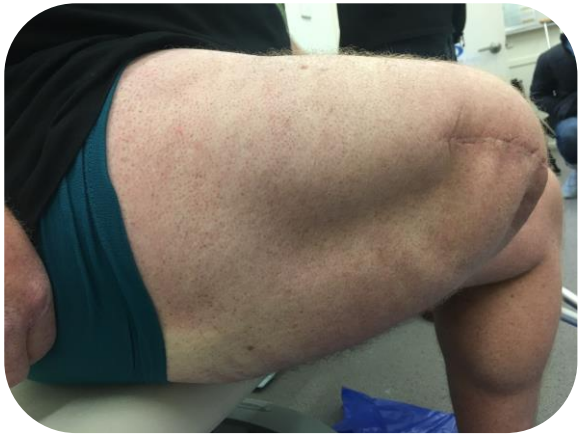
- Evaluate tissue consistency with the patient sitting down
- Classify the tissue as either soft or firm to establish appropriate liner:

<u>Soft tissue:</u>

  – Minimal shape change with contraction

<u>Firm tissue:</u>

  – Noticeable shape change with contraction



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Subischial Casting Method

- Don the liner rolling as high onto the residual limb as possible
- Proximal portion of liner often sits at the gluteal fold
- Deflect liner up to 50mm, increasing compression of the soft tissues and helps create the shape for casting

[6]Prosthetics and Orthotics International: Northwestern University Flexible Subischial Vacuum Socket for persons with transfemoral amputation-Part 1: Description of technique. Stefania Fatone and Ryan Caldwell

Subischial Casting Method

- Wrap in cling film
- Don thin sock and mark Anterior midline
- Measure in 3cm increments
- Take snug M-L measure from proximal edge of liner at perineal level, noting how much compression can be achieved when pushing sub-trochanterically

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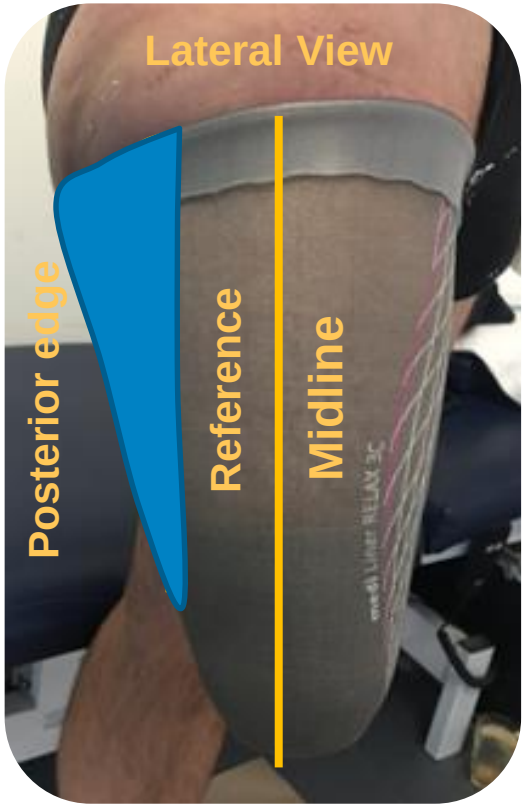
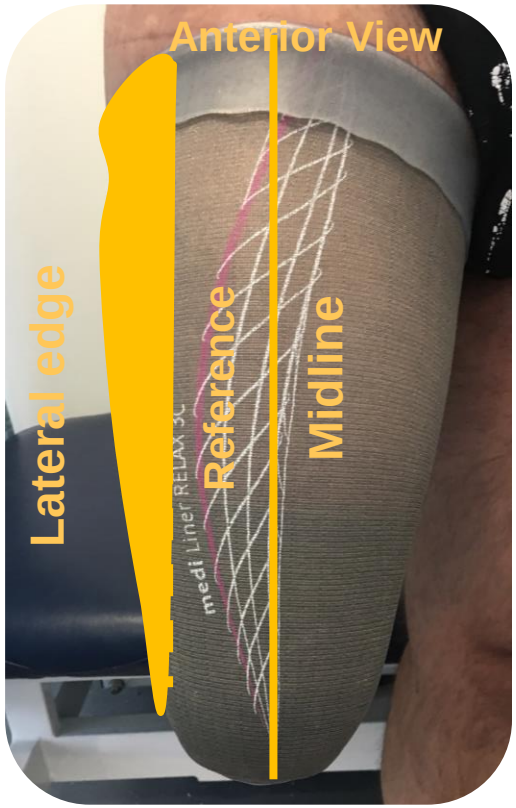
Subischial Casting Method

- Cast with client sitting, with residual limb flexed at 90° and abducted using Fibreglass tape
- Start casting proximally on the lateral side, wrapping medially
- Take note of how easy/hard it is to remove the mould
- Classify the residual limb as symmetrical or asymmetrical
- Casting tape: 404DP

[6]Prosthetics and Orthotics International: Northwestern University Flexible Subischial Vacuum Socket for persons with transfemoral amputation-Part 1: Description of technique. Stefania Fatone and Ryan Caldwell

Classify residual limb as Symmetrical or Asymmetrical





- View anteriorly and laterally to determine whether the lateral and posterior edges of the residual limb are parallel to midline or if they angle away from midline proximally
- **Symmetrical:** angulation away from midline is of similar degree for both the lateral and posterior edges
- **Asymmetrical**: if one edge angles away from midline more than the other

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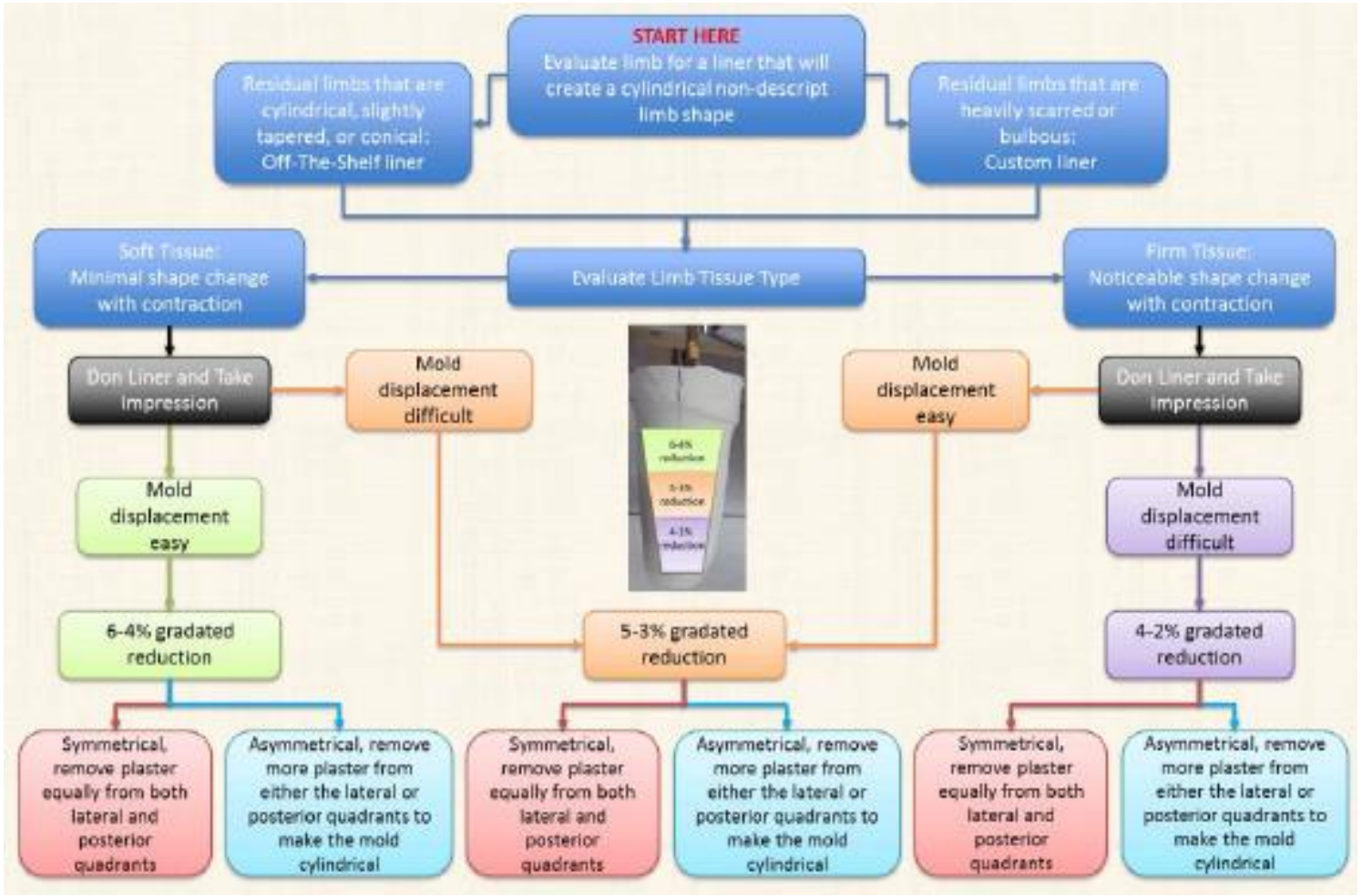
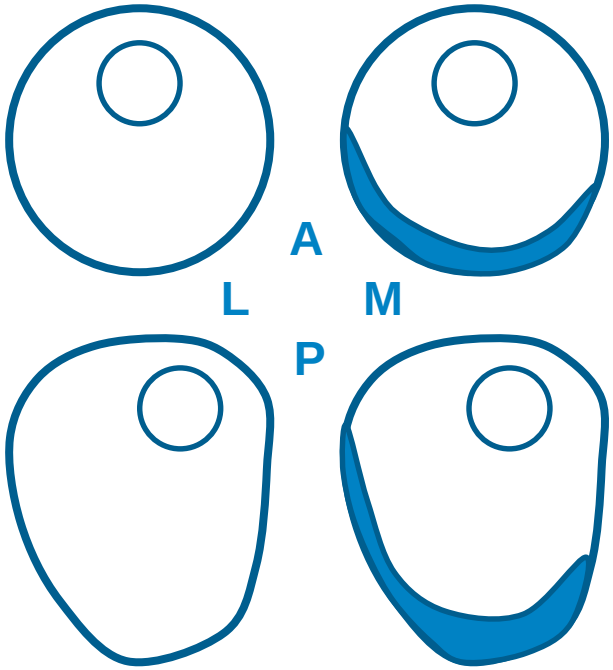
Modification Algorithm



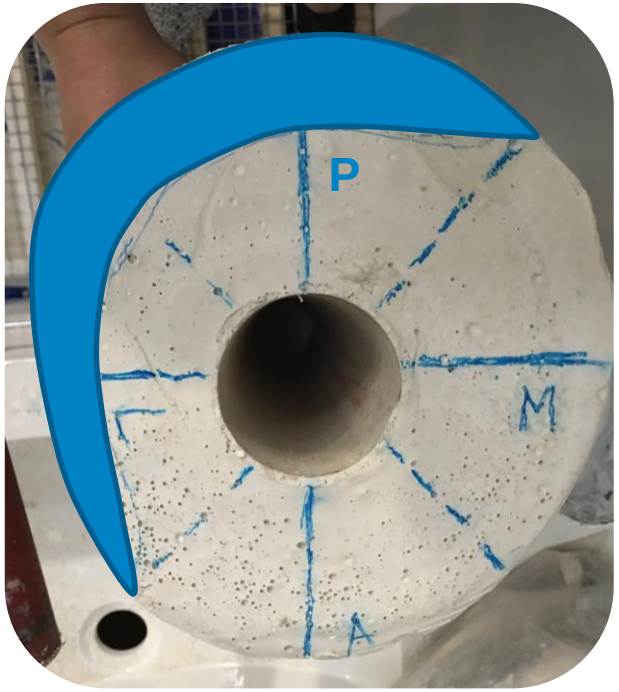
[8]Development of the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket for Persons with Transfemoral Amputation Ryan Caldwell, CP/L FAAOP, and Stefania Fatone, PhD, BPO(Hons), Northwestern University Prosthetics-Orthotics Center (NUPOC)

Cast Modification

Symmetrical



Asymmetrical



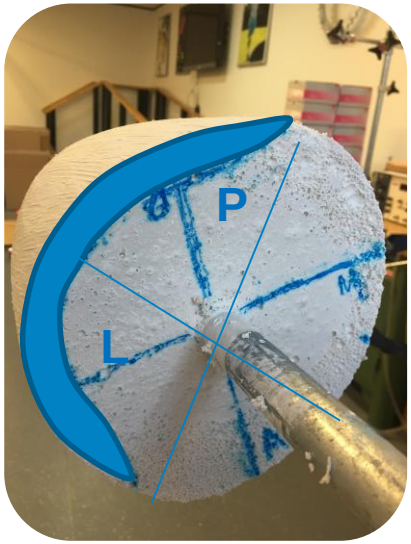
Asymmetrical cast example

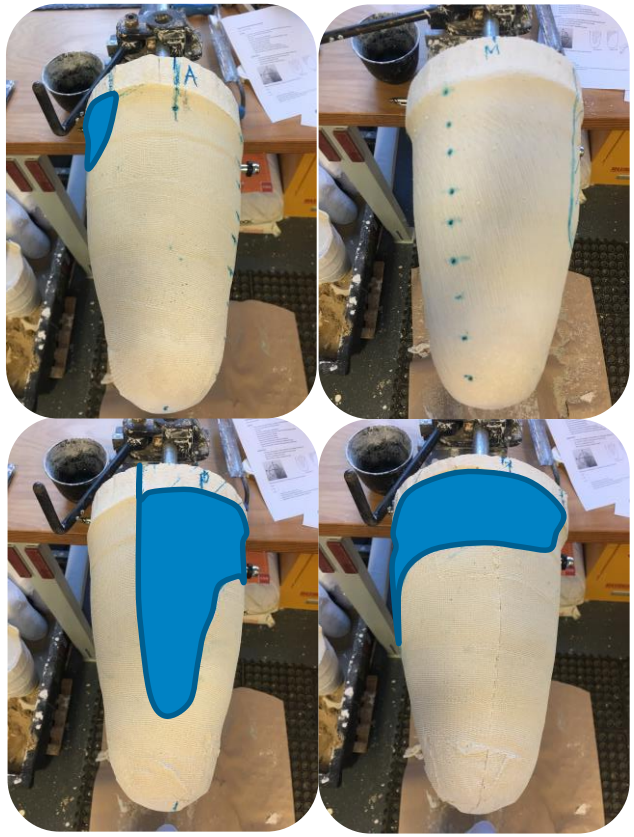
Plaster Removed

[6]Prosthetics and Orthotics International: Northwestern University Flexible Subischial Vacuum Socket for persons with transfemoral amputation-Part 1: Description of technique. Stefania Fatone and Ryan Caldwell

Modification

- Transfer Anterior reference mark and line of progression to positive model
- Reduce cast to recommended reductions
- Focus reduction in the proximal posterior and lateral area, flattening them into a ‘boomerang’ shape
- Blend in these modifications creating a round barrel like shape
- Smooth rest of cast removing any bumps



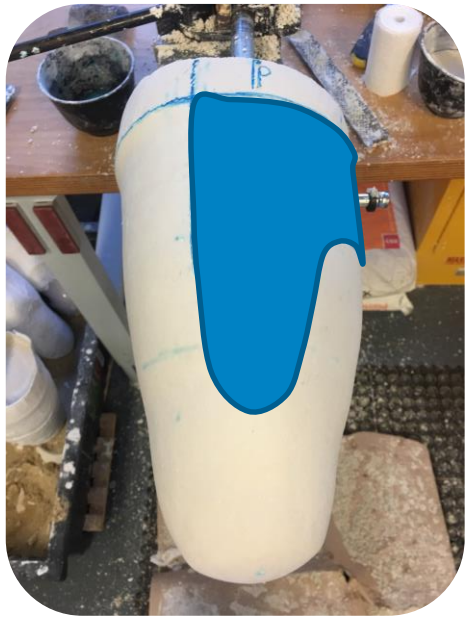


[8]Notes from AAOP meeting, Chicago Illinois, March 2017 “NU-FlexSIV workshop’

Positive model

Anterior

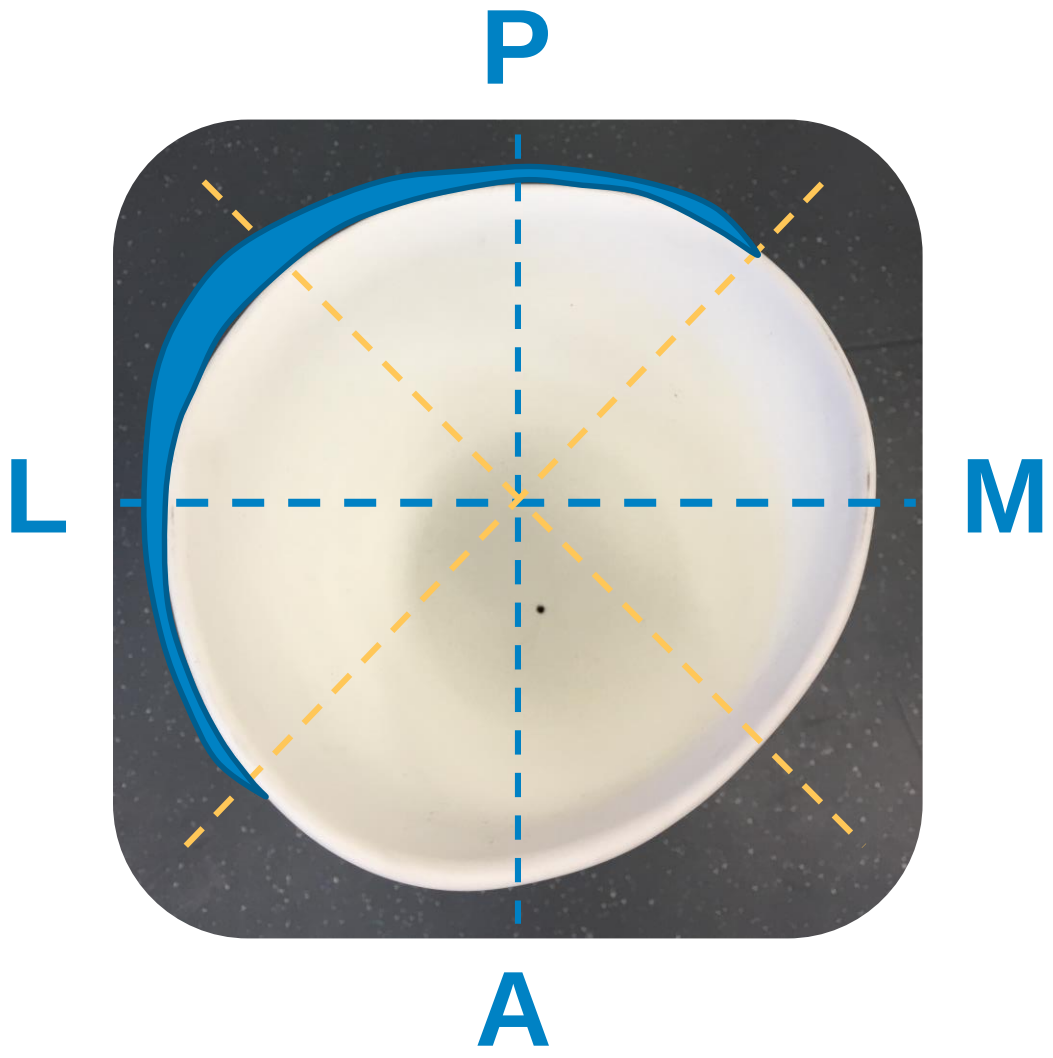
Lateral



Posterior

[8]Notes from AAOP meeting, Chicago Illinois, March 2017 “NU-FlexSIV workshop’

Nu-FlexSIV Socket



Evaluating Check Socket

- Assess circumferential volume using socks
- Asses proximal trim lines- looking to sit 25mm below IT and 50mm below GT
- Deflect liner over proximal top of socket
- Seal using Iceross Sleeve to seal against deflected liner
- Check for lateral gapping
- Proximal tissue should feel firm

[9]Notes from AAOP meeting, Chicago Illinois, March 2017 “NU-FlexSIV workshop’

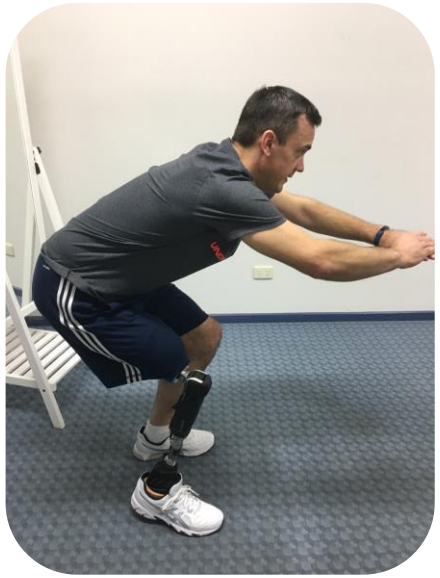
Evaluating the check socket

- Dynamic fitting on socket to assess volume/fit and control
- Typical socket adjustments will be in the posterior or lateral areas (gapping may be present)
- Recommend not to trial rigid socket any longer than initial check fit as the rigid check socket will not feel comfortable proximally and can also cut into the liner
- When satisfied with volume and shape of check socket go to definitive socket
- Elevated vacuum is not imperative however it has been shown to **increase socket comfort**
- Definitive Socket utilises Flex EVA (distributed by Össur) and carbon outer socket
  - Carbon socket trim lines cover 1/2 to 2/3 of flexible socket
  - Carbon socket can be lower on posterior side

[9]Notes from AAOP meeting, Chicago Illinois, March 2017 “NU-FlexSIV workshop’

Donning

Results: Increased ROM



- Increased ROM due to lower proximal trim lines
  - Donning/Doffing shoes
  - Squatting
  - Picking up objects
  - Stretching lower back
  - Toileting without removing prosthesis

Results: Comfort without compromised stability

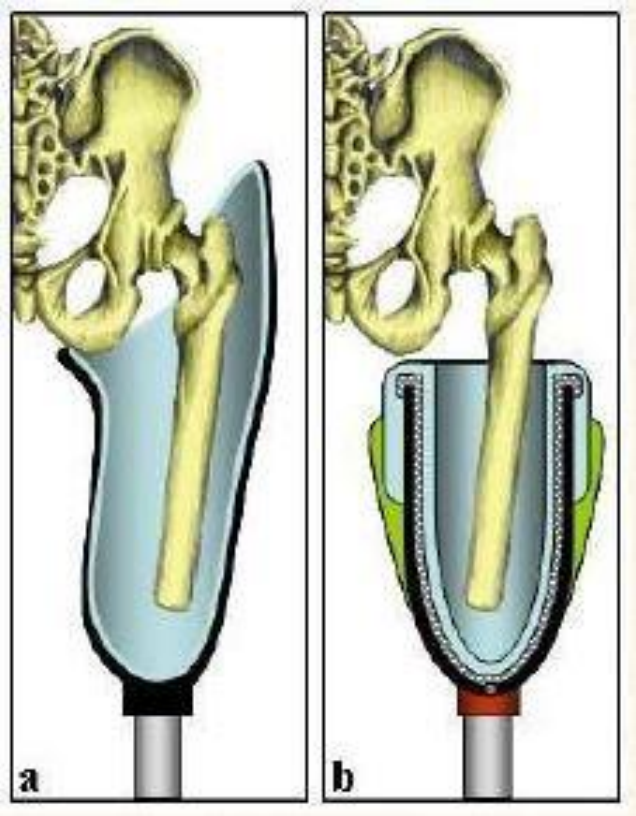
Definitive socket

- Materials:

- Flex EVA White- 10mm: 1820610
- Flex EVA White- 12mm: 1820612
- Flex EVA White- 15mm: 1820615

- Casting tape: 404DP

Subischial Sockets -Training Considerations



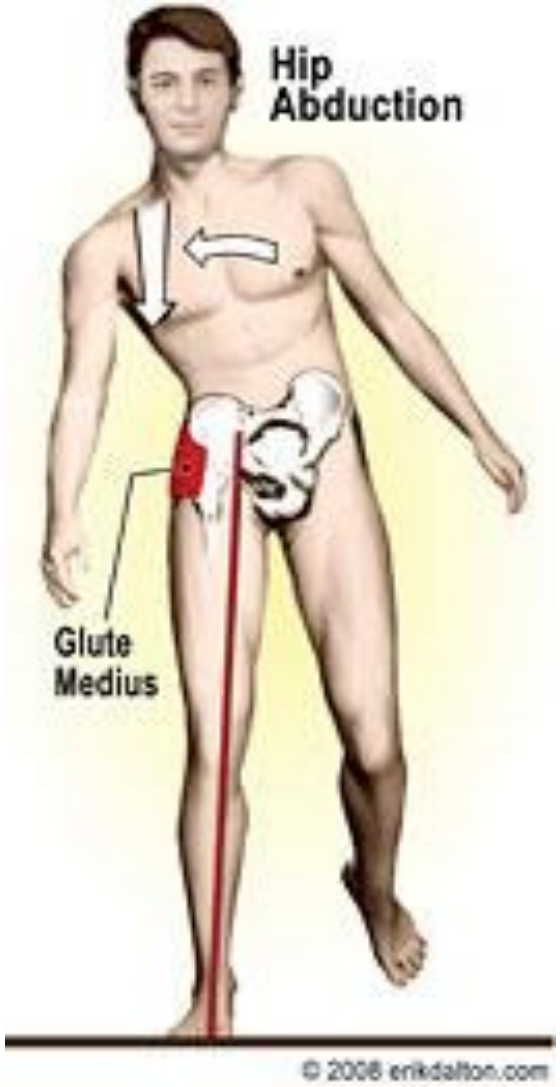
- Lower trim lines of the Subischial socket indicate a need for training to optimise the functioning of the Gluteus Medius and prevent lateral trunk bending.
- More attention to the hip extensors on stair ascent.

[7]Development of the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket for Persons with Transfemoral Amputation
Ryan Caldwell, CP/L FAAOP, and Stefania Fatone, PhD, BPO(Hons), Northwestern University Prosthetics-Orthotics Center (NUPOC)

What happens if the pelvis doesn’t shift to the stance side?

- Please Stand up
- Place your hands on your iliac crest
- Stand on your Left leg **BUT DON’T ALLOW YOUR PELVIS TO MOVE LEFT**
- How can you achieve it?

Lateral Trunk Bending

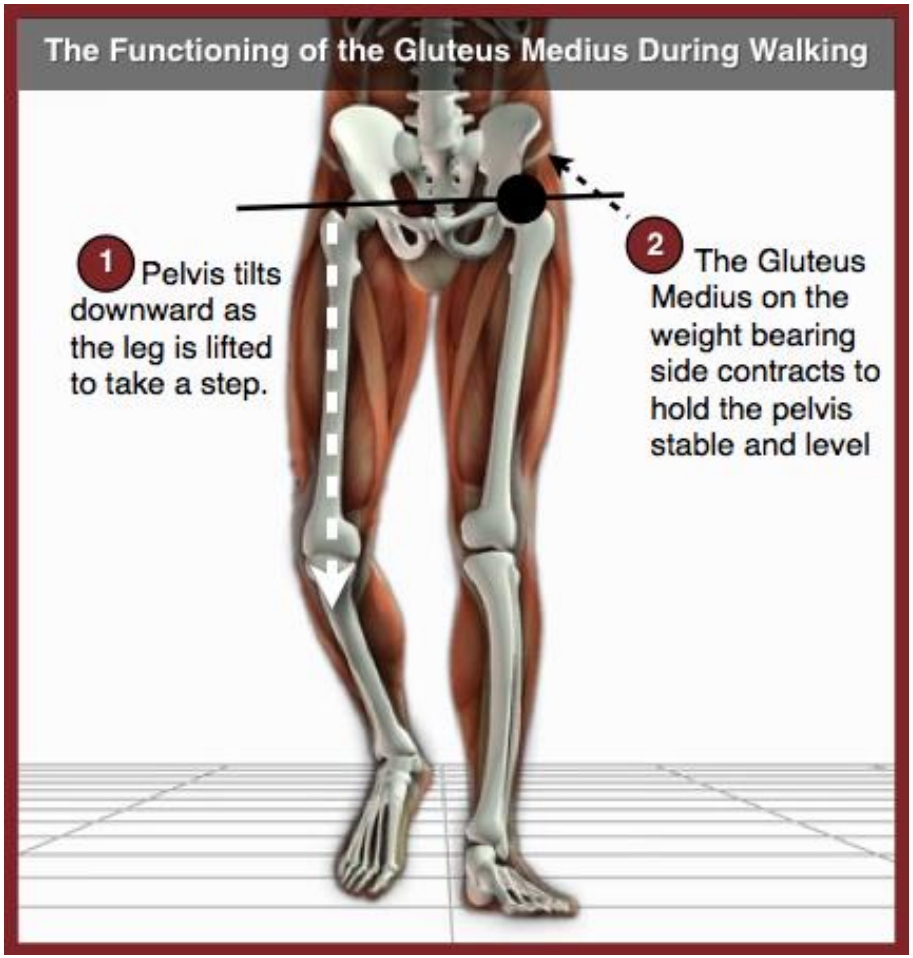


If Lateral Pelvic Shift does not occur, your weight will be shifted by translation of the upper body to the weight bearing side…

Normal Gait:

- Pelvis tracks laterally toward the weight bearing side
- Lateral Pelvic Shift reaches its maximum just after midstance

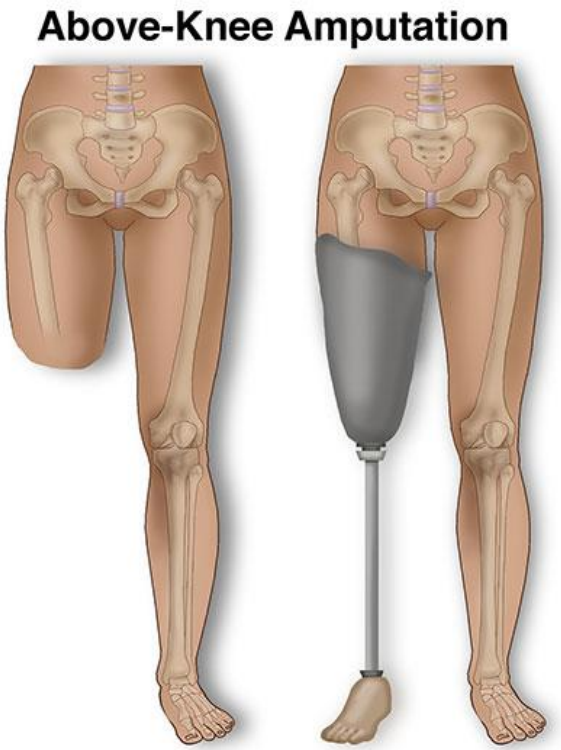
Normal Gait: Control of Lateral Pelvic Shift



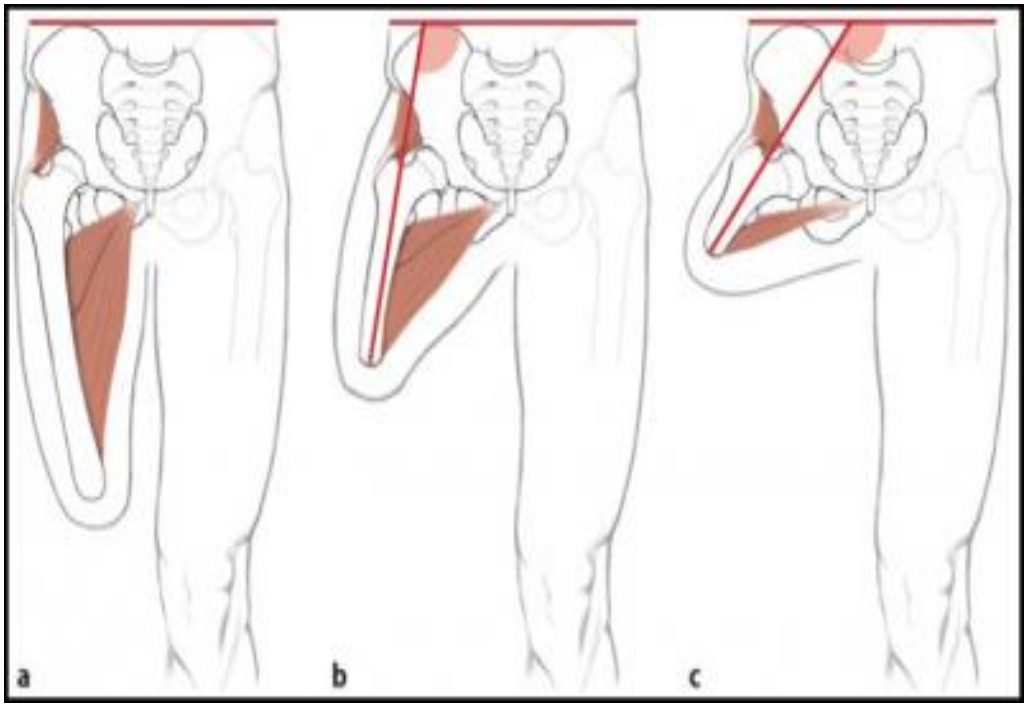
- Gluteus Medius strength and control (eccentrically)
- Rotation of the upper body in opposition to the pelvis
- Core stability

Effectiveness of the Gluteus Medius after Amputation.

- Destabilisation of the lever's contact with the ground.
- Motion of the femoral remnant in the socket.
- Weakness of Glute med.
- Decreased core abdominal strength and control on affected side due to decrease in weight of limb.

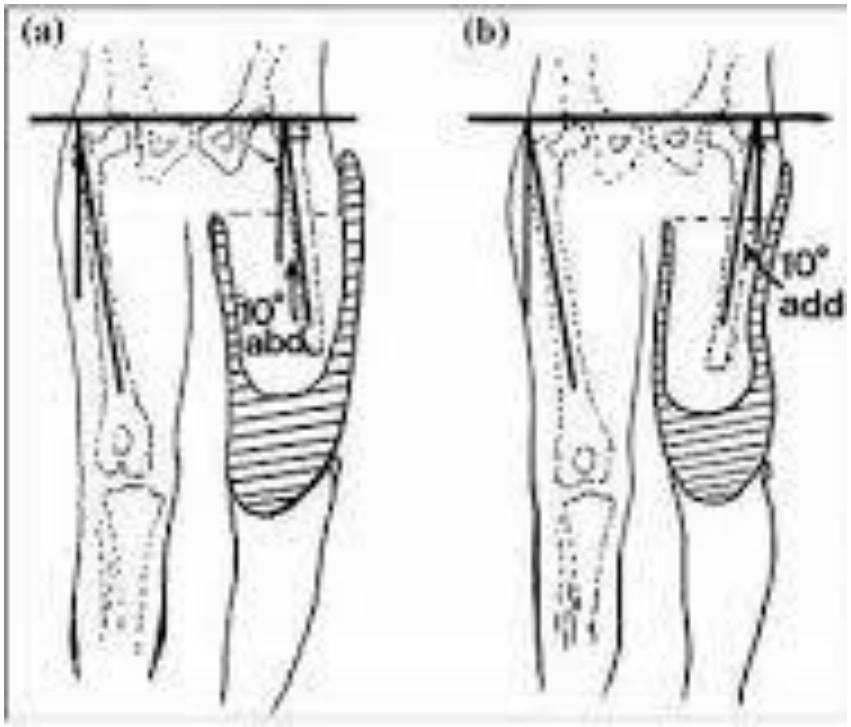


Effectiveness of the Gluteus Medius after Amputation



- Sectioning of the adductors
- Abductors remain intact- may become shortened & overactive.
- Difficulty in achieving lengthened position of Abductors to achieve socket adduction.

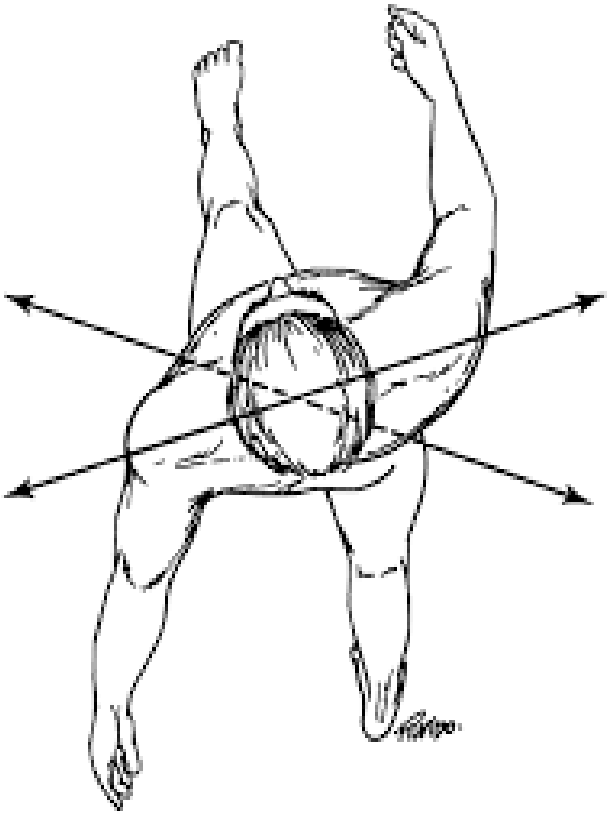
Action of the Abductors in Stance Phase



For maximal effectiveness the abductors need to be:

- Lengthened by adduction of the femoral remnant.
- Working ECCENTRICALLY.
- Unimpeded by pain.

Associated loss of upper body rotation in opposition to the lower body



Gait Patterns with Subischial Socket Design

The Importance of Lateral Pelvic Shift and Rotation

Strategies for Increasing Weight Bearing and Lateral Pelvic Shift

- Use scales
- Biofeedback
- Weight transference exercises & mirror feedback
- Decrease contralateral hand support
- Add resistance to the activity

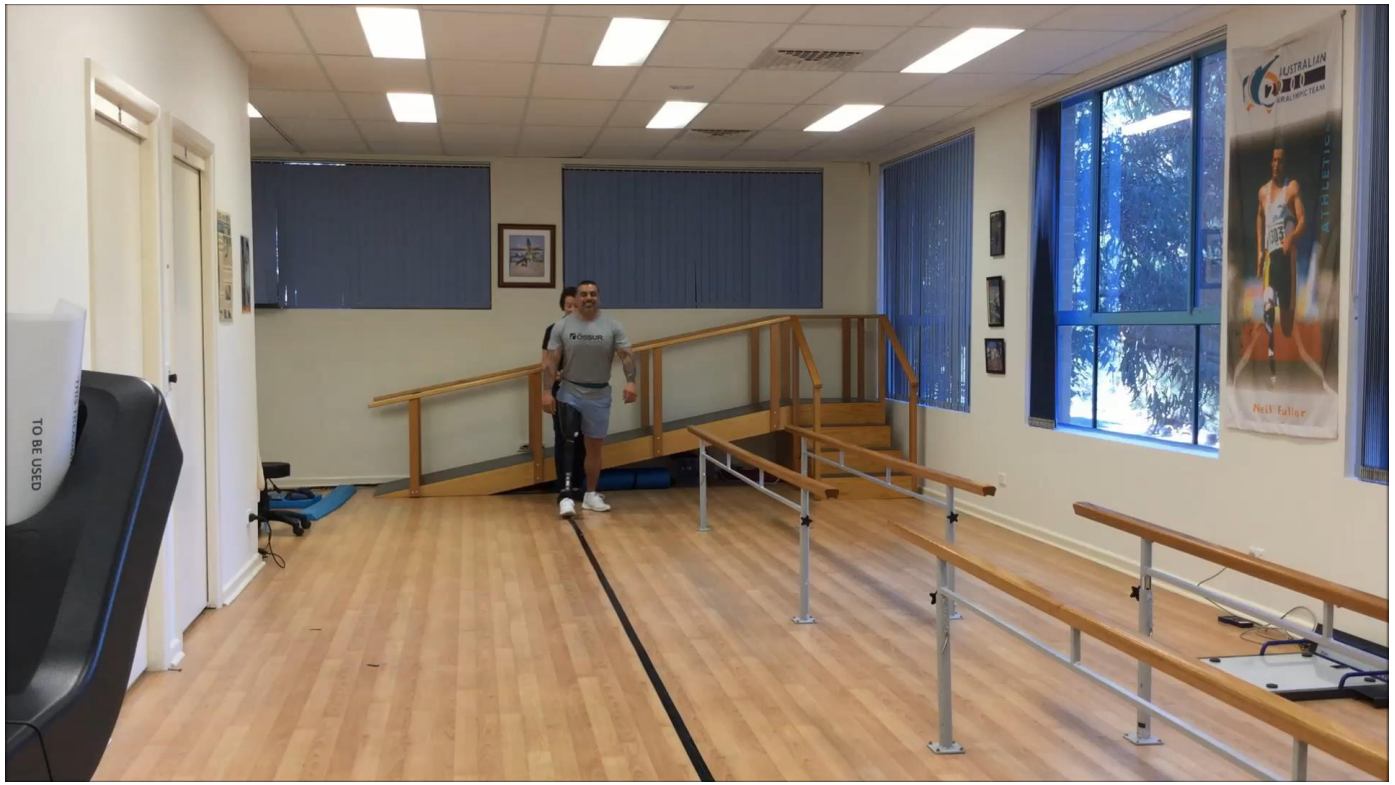
Resisted Lateral Pelvic Shift Exercises

Exercises To Increase Abductor Functioning:

- Strengthening throughout range

- Stability

Adding Resistance to the Activity

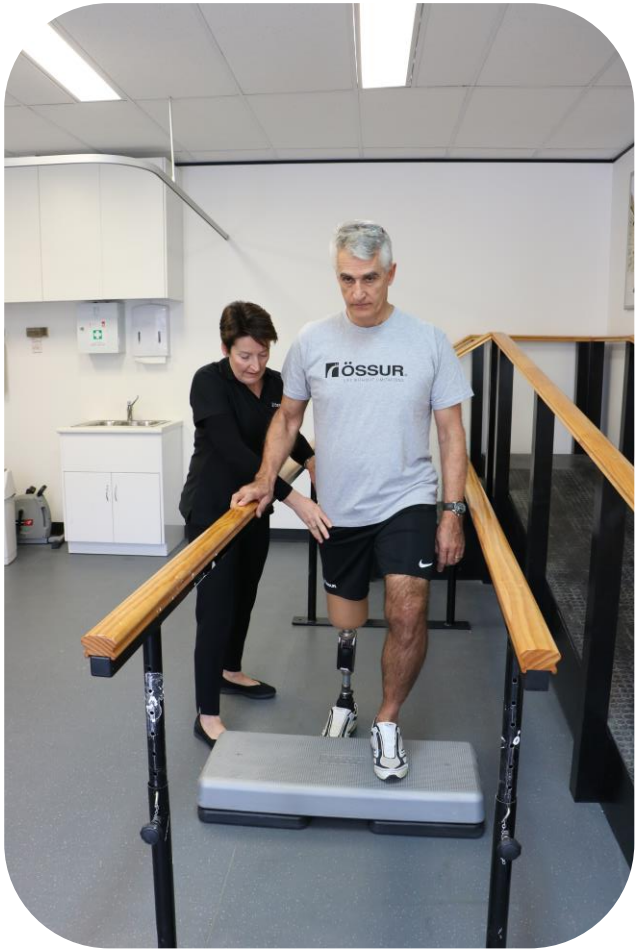


Yitiger,K.2002. Resistive Gait Training leads to:

- Increased weight bearing
- Increased stride length
- Decreased step length on the amputated side
- Increased step length on the sound side
- Increased self selected speed

Practical Demonstrations

- TheraBand resistance:
  - Lateral Pelvic shift
  - Resistive gait training
- Sit to stand with resistance
- Upper body rotation
  - Facilitated walking



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7. Prosthetics and Orthotics International: Northwestern University Flexible Subischial Vacuum Socket for persons with transfemoral amputation: Part 2 Description and Preliminary evaluation. Stefania Fatone and Ryan Caldwell
8. Development of the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket for Persons with Transfemoral Amputation Ryan Caldwell, CP/L FAAOP, and Stefania Fatone, PhD, BPO(Hons), Northwestern University Prosthetics-Orthotics Center (NUPOC)
9. Notes from AAOP meeting, Chicago Illinois, March 2017 “NU-FlexSIV workshop’

Pro-Flex® Family Update

- Overview of Pro-Flex® mechanics
- Pro-Flex® medical benefits
- Recap of Pro-Flex® XC and Pro-Flex® LP
- Introducing Pro-Flex® XC Torsion
- Introducing Pro-Flex® LP Torsion

Advancing medical and mobility benefits

Pro-Flex® delivers the following functional improvements and benefits:
(Data reflects direct comparison to Vari-Flex – on file at Össur):

- Increased ankle range of motion of 82.2%
  (82.2% on level ground; 104.8% and 84.3% for ramp descent and ascent)

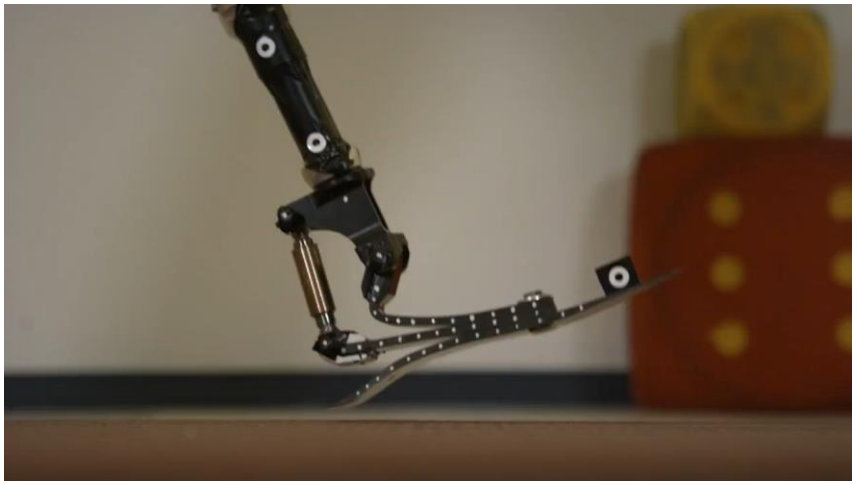
- Increased ankle power of 93.3%, resulting in increased push-off at terminal stance (93.3% on level ground; 150.0% and 100.0% for ramp descent and ascent)

- More physiological center of pressure movement during roll-over extends stance phase period of support (on the affected side)

- This combination of functional features delivers overall medical benefit:
  Reduced impact of 11% on the sound side
  Reduced varus moment of 15% on the sound side

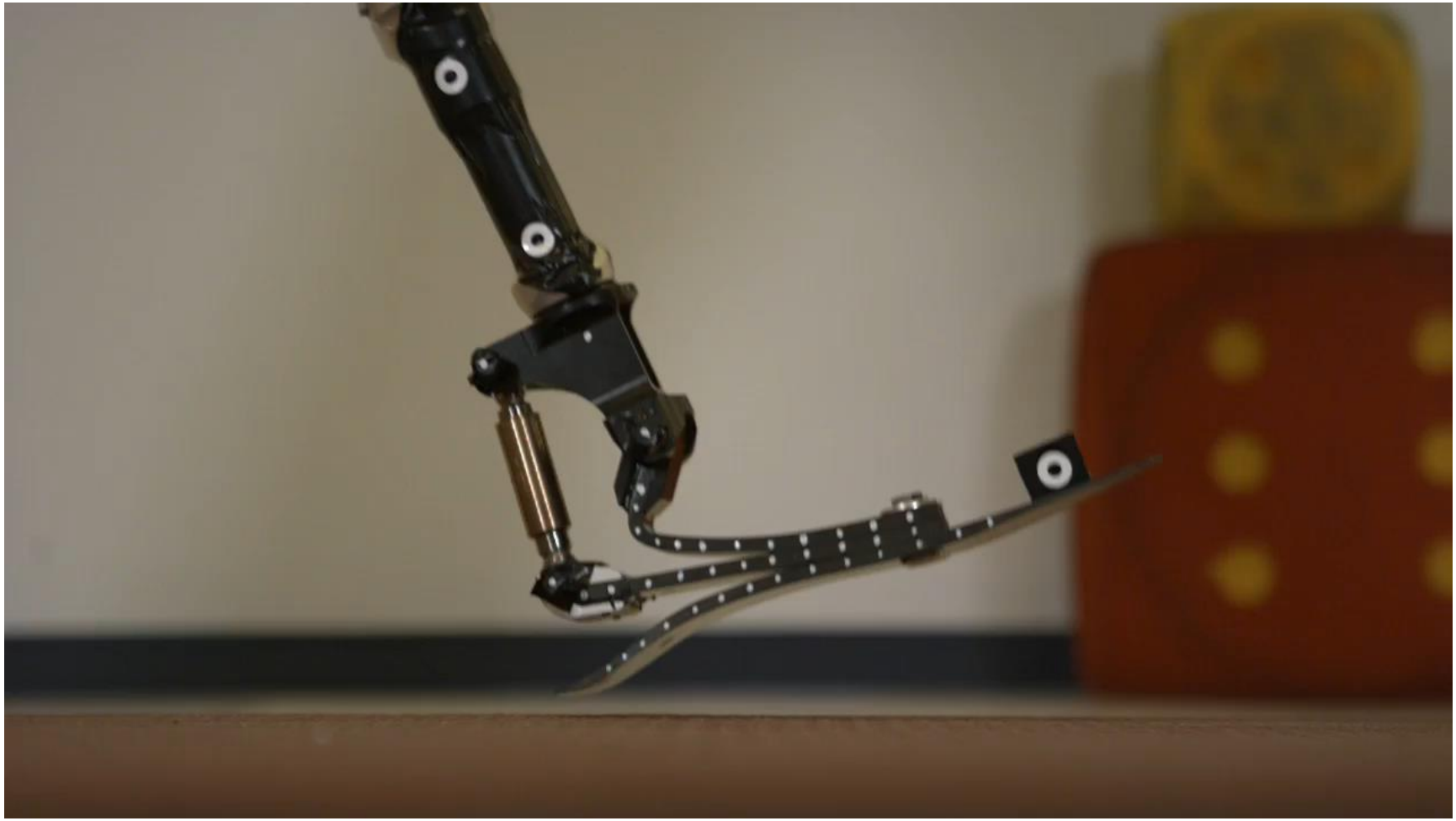
Pro-Flex®- K2-K3

- Interaction of 3 carbon fiber blades with new pivot technology
  - **Polycentric ankle geometry**
  - Blades interact to control stiffness and rate of Plantarflexion and Dorsiflexion
- Low Stiffness**: High Flexibility in the midrange** gives a greater range of motion of 27 degrees
- High Stiffness in Terminal Stance to Pre-swing assists in Propulsion. **Power is almost x2 that of a Vari-Flex.**
- Pro-Flex® delivers:
  - Increased ROM
  - Powerful push off
  - Physiological progression of the COP

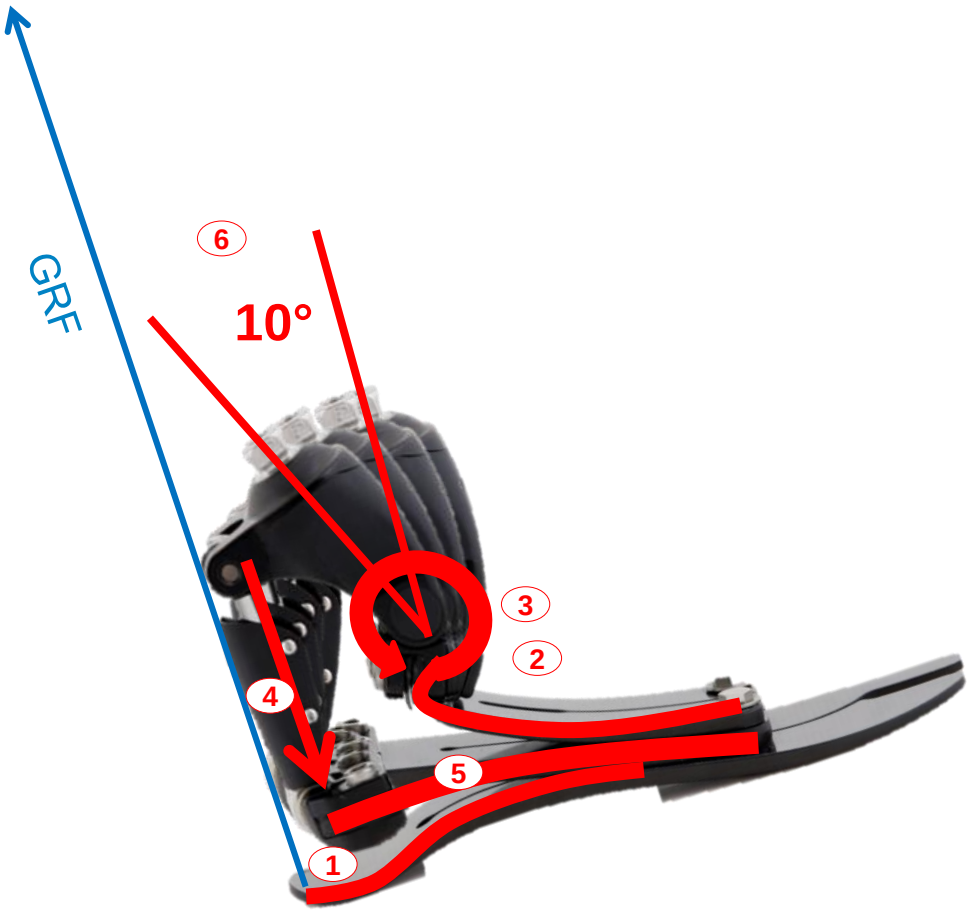


Without Hydraulics or Microprocessor technology Pro-Flex® delivers powerful push off, 12% less than a BIOM

Pro-Flex® Mechanics



Loading Response



1. Active Heel compresses under load
2. Upper Blade compresses under load

So far, just like a normal ESAR Foot

In addition, Pro-Flex provides:

3. Backward rotation around main pivot
4. Back-link transfers load onto mid-lever
5. Mid-lever loads and deflects downward
6. 10° real plantarflexion

Mid-stance

Rotation through physiological centre of rotation
Maintain full toe lever for maximum mechanical advantage

Terminal Stance

1. Sole blade compresses storing energy
2. Upper blade compresses storing energy

So far, just like a normal ESAR Foot

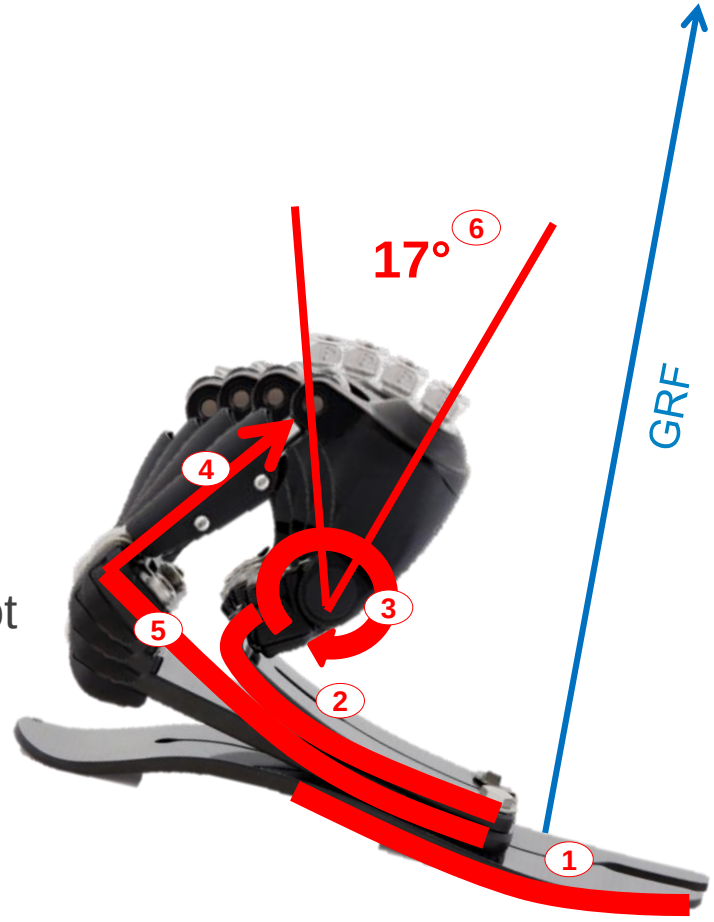
Terminal Stance

1. Sole blade compresses storing energy
2. Upper blade compresses storing energy

So far, just like a normal ESAR Foot

In addition Pro-Flex provides:

3. Forward rotation around main pivot
4. Back-link “pulls” mid-lever up
5. Mid-lever deflects upward
6. 17° real dorsiflexion



Push-Off

1. Energy return from the compressed sole blade
2. Energy return from compressed upper blade

So far, just like a normal ESAR Foot

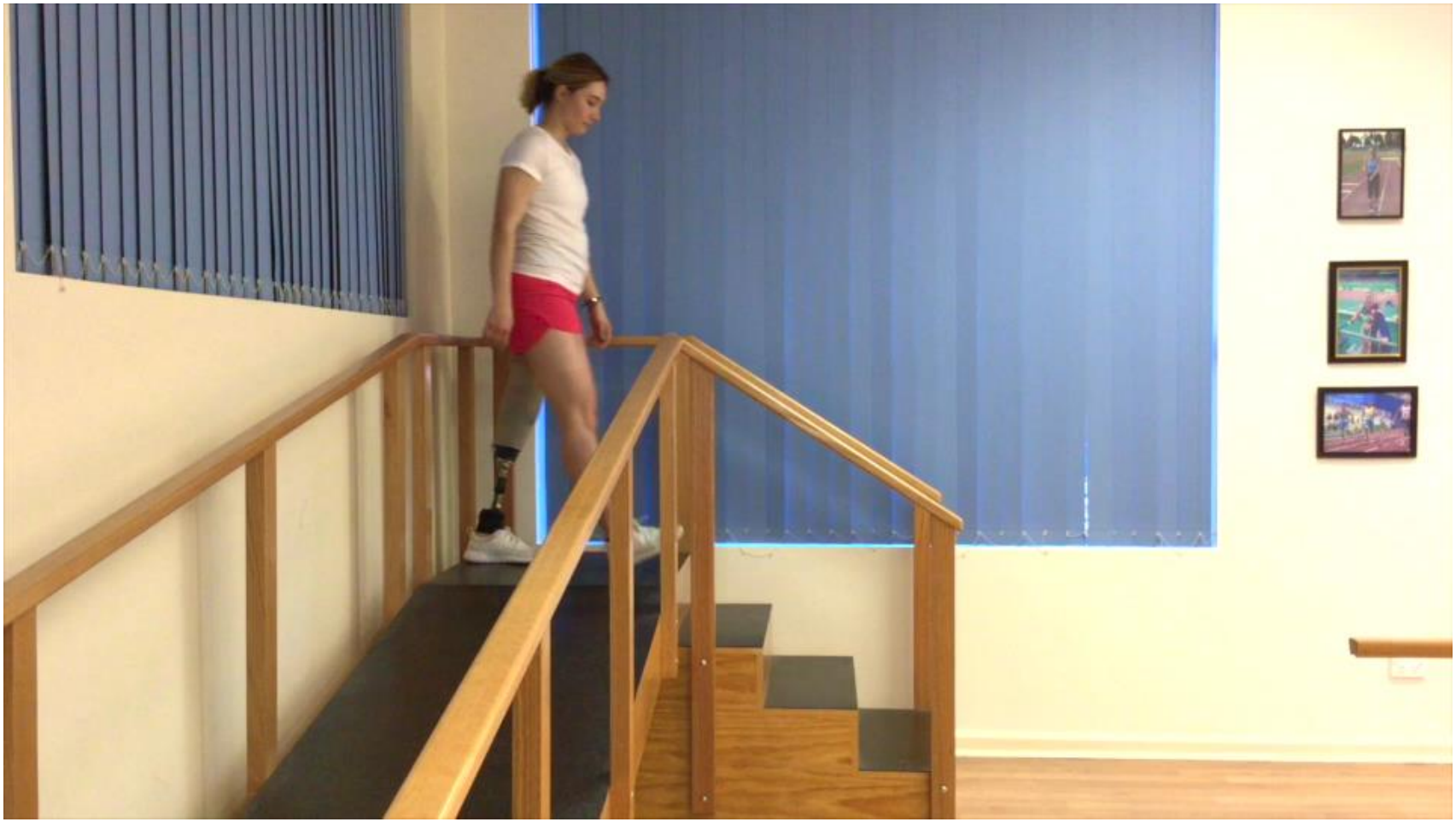
In addition Pro-Flex provides:

3. Mid-lever creates active plantarflexion moment
4. Main pivot undergoes backward PF-torque
5. At toe-off the mechanically powered ankle generates 2.9W/kg*

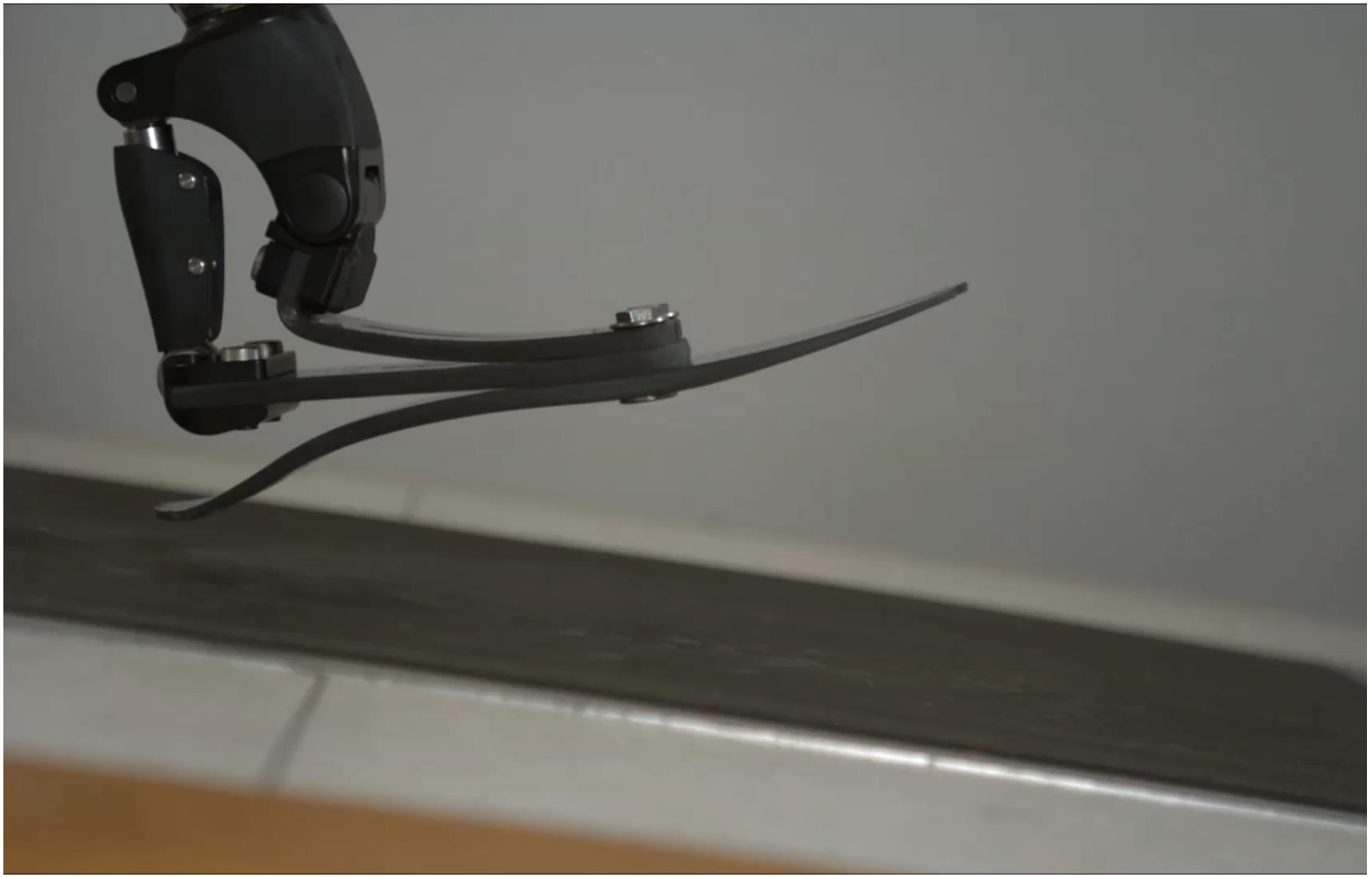
***93% more than ESAR feet (1.5W/kg)**
***only 12% less than BIOM (3.27W/Kg)**

Pro-Flex® Stair ascent

Pro-Flex® Stair ascent and descent



Pro-Flex® Ramp descent



More physiological ankle power

Mechanical testing aim: separate stiffness measurement for ankle motion depending on location in stance phase

- **Low stiffness around mid-stance**: reduce moment and pressure on the residual limb
- **Higher stiffness in late stance:** create higher ankle power

The high energy return along with progressive stiffening, similar to what seen in anatomical ankle, is an indication of a powerful push-off during late stance.

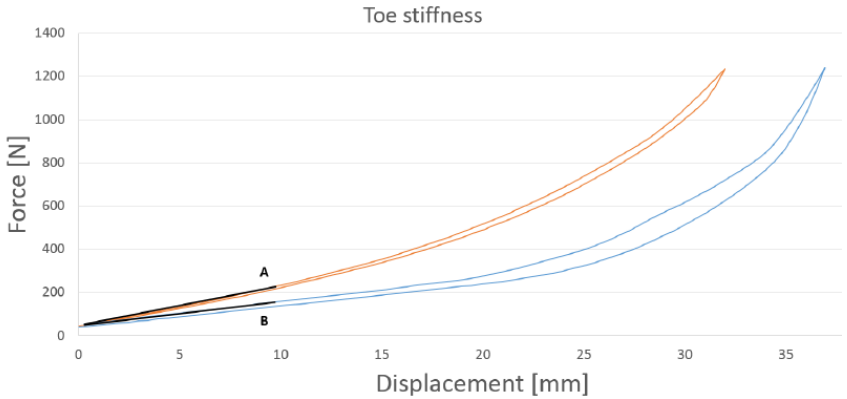


Figure 1: Stiffness curves for Pro-Flex™ (B) and Vari-Flex® (A). The black lines show the linear part of each curve.

Pro-Flex® Medical Benefits

- Osteoarthritis (OA) in the sound side knee joint is 17 times higher than in age-matched non-amputees[1]
- Pain is twice as common
  - This is a result of asymmetrical gait, increased impact and more time spent on the sound side
- Pro-Flex® is tackling the principle mechanical causes of OA for people with limb loss:
  - Helping to enhance gait symmetry (Improved progression of COP)
  - Reduce sound loading by reducing peak impact by 11%
  - Reducing knee varus moment by 15%
- The powerful push off means the bodys centre of pressure is less elevated on the prosthetic side at the time of stepping forward onto the sound side.
- The result is a smoother more symmetrical gait and reduced impact on the sound side.

1Struyf, Pieter A., et al. "The prevalence of osteoarthritis of the intact hip and knee among traumatic leg amputees." Archives of physical medicine and rehabilitation 90.3 (2009): 440-446

User Profile

- Transtibial, Knee disarticulation, Transfemoral, and Hip disarticulation amputees
- K-level: K2 and K3
- Impact level: Low to Moderate
- ADL's and recreational activities like hiking (uneven ground, ramp surfaces, stairs)
- Weight limit: 125 kg
- Pro-Flex is NOT intended for high impact use

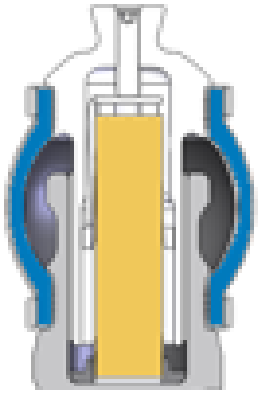
Pro-Flex® XC- K3-K4

Unity Compatible

- Upgrade to the Vari-Flex XC
- Increased ankle motion and reduced sound side loading when compared to Vari-Flex
- **Similar ankle motion & sound side loading when compared to Vari-Flex XC (10mm vertical compression due to C shaped design)**
- **Improved roll-over when compared to Vari-Flex XC**
- **Easier to cosmetically finish than Vari-Flex XC**
- Increased Function and Satisfaction when compared to Vari-Flex and Vari-Flex XC

Pro-Flex® XC is recommended for clients up to 166kg that engage in moderate to high impact levels activities on a regular basis.

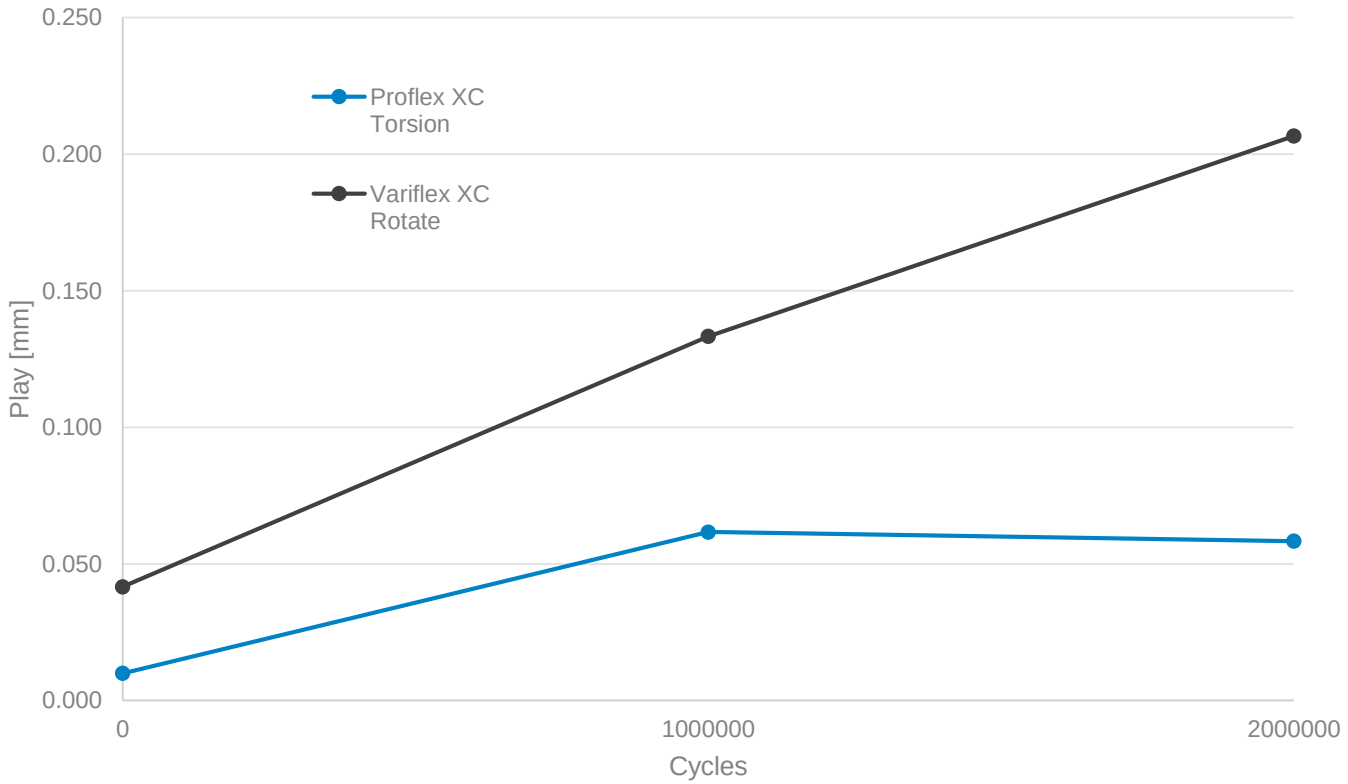
Pro-Flex® XC Torsion



- The torsion-shock unit compensates for physiological rotation and vertical shock absorption of lost joints
- Increases comfort
- Reduces stress on the residual limb.
- Axial compression up to 6mm
- Improved durability over the Vari-Flex XC Rotate
  - Adjusted materials to ensure complete compatability
  - Increased surface area of the rod
  - Self lubricating rod with thicker grease
  - Knurl surface pattern which holds the torsion cell in place is more rough to prevent slip
- Unity compatible

Comparison test: Pro-Flex XC Torsion

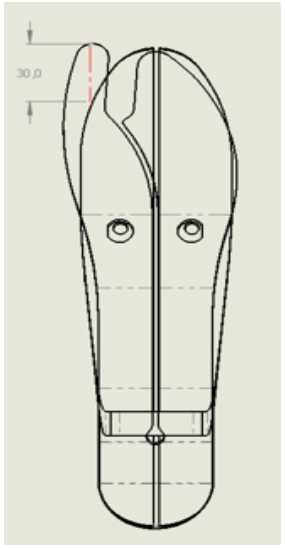
Development of play for Pro-flex XC Torsion VS Vari-flex XC Rotate



Pro-Flex® LP- K1-K4

Unity Compatible

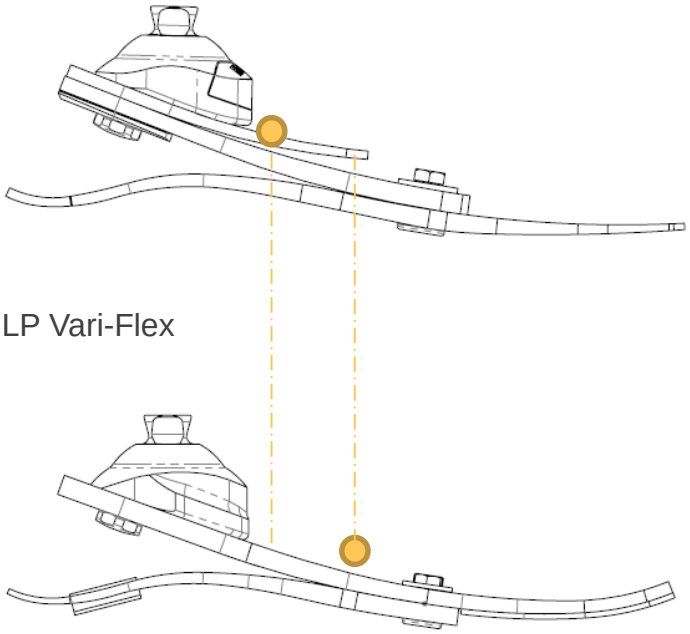
- Pro-Flex® LP offers greater ankle range of motion than other feet with low build height (LP Vari-Flex)
- Improved physiological gait
- Increased function and satisfaction



Pro-Flex® LP is recommended for clients up to 166kg with longer residual limbs (where clearance is an issue) and moderate to high impact levels.

Pro-Flex® LP

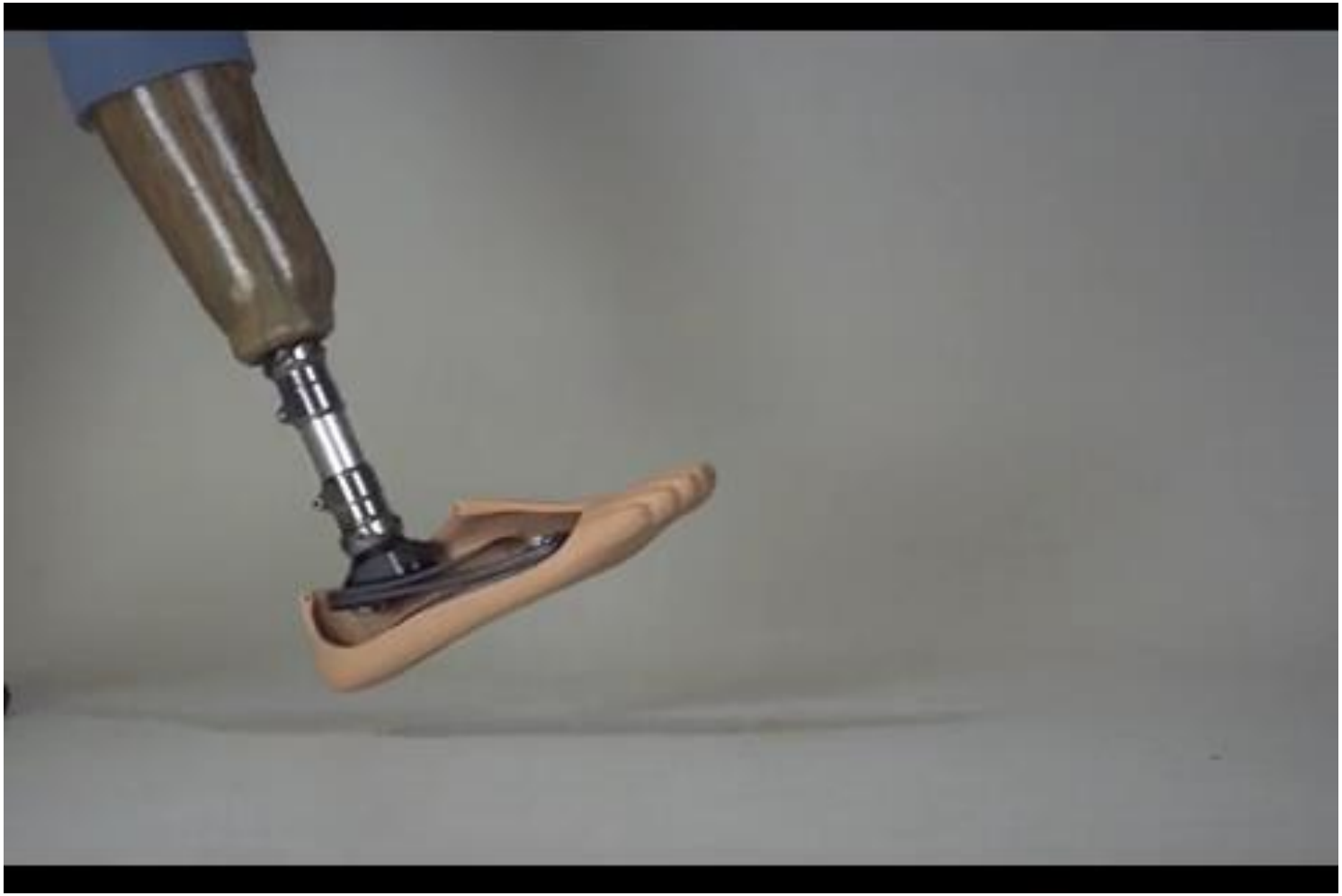
Pro-Flex® LP



LP Vari-Flex

- Pro-Flex® LP introduces a patent pending blade lay-up technology.
- **Mid-blade is reversed tapered** allowing more flex anteriorly.
- Posterior part of the mid-blade is thinner and gets gradually thicker anteriorly towards the sole blade attachment bolts.
- Functional ankle joint center of Pro-Flex® LP is closer to anatomical than LP Vari-Flex

Level ground walking

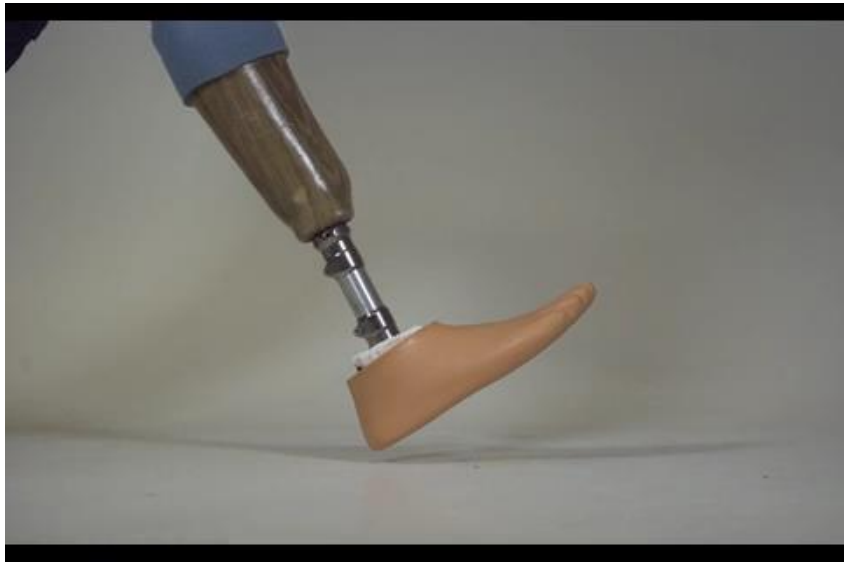


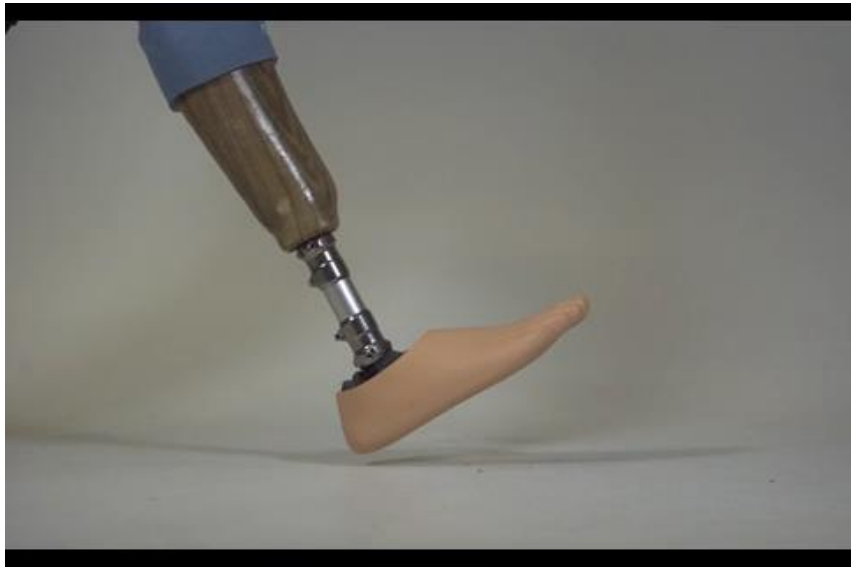
Level ground walking

- Foot flat
- Range of motion

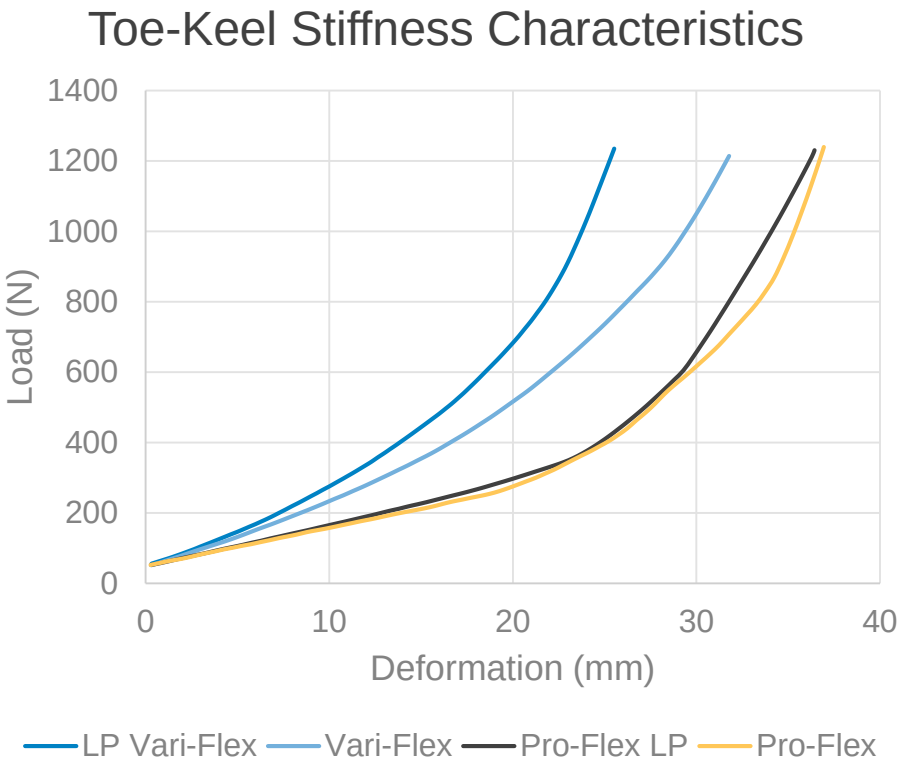
  LP Vari-Flex

  Pro-Flex® LP





Test Results



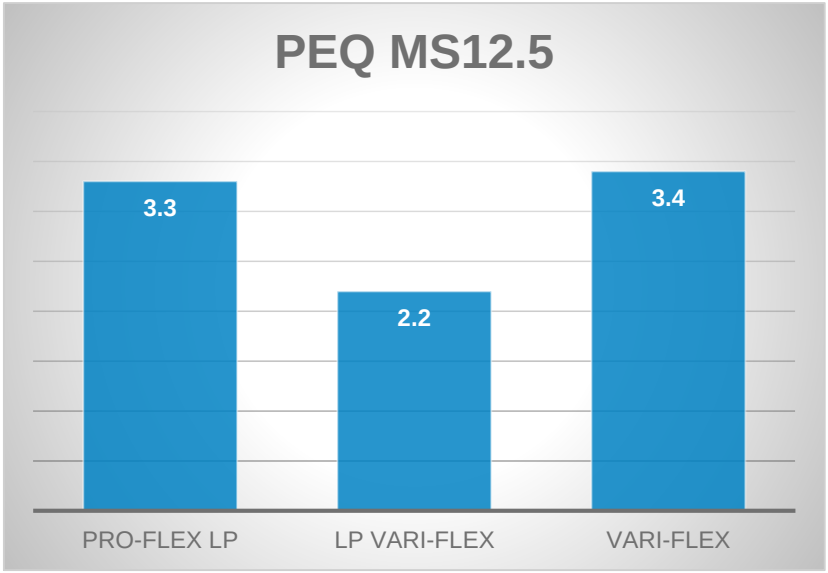
All samples cat 5 size 27 tested with foot cover.

- **Progressive stiffness** of Pro-Flex® LP
- **Much lower stiffness during the first part** of the loading curve for Pro-Flex® LP compared to LP Vari-Flex
- **Clinically, this indicates:**
  - lower resistance to initial dorsiflexion for Pro-Flex® LP, meaning **less moment needed** from the residual limb to load the foot
  - higher displacement for the Pro-Flex® LP indicates **more ankle range of motion** with the same load.

Test Results

- Greater user satisfaction when compared to LP Vari-Flex (almost equal to Vari-Flex)*

- User comments:
  - feels like foot has more give to it
  - lot of energy in toe
  - very smooth
  - roll-over feels more natural



*testing performed on 4 users indicates differences between feet.

Pro-Flex® LP Torsion

The middle blade **is reversed tapered** allowing for more dynamics

Posterior part of the blade is thinner and gets gradually thicker towards the sole blade attachment bolts.

Difference in approximate location of the functional joint center between Pro-Flex LP and LP Vari-Flex.

Torsion unit for reducing shear stress and providing shock absorption

ÖSSUR ACADEMY

Advancing Clinical Outcomes with RHEO KNEE® and RHEO KNEE® XC

AOPA 2017 - Technical and Training Workshop

Sarah Mulroy (Clinical Specialist)

Cathy Howells OAM (Physiotherapist)

Optimising Outcomes Workshop

- **Subischial Socket design**
  - Unity Elevated Vacuum
  - Subischial Socket design
  - Casting method
  - Training considerations
- **Updated Pro-Flex Family products**
- **RHEO KNEE Update**
  - Updated functions of the RHEO KNEE
  - How to Programme
  - Training considerations
- **Mechanical Knee Considerations**
  - Overview of mechanical knee range
  - Introducing the PASO Knee
  - Training considerations
  - Learning to Run

Introducing new RHEO KNEE and RHEO KNEE XC functions

- **New optional settings to enhance stability in stance and swing for lower active users**
- Optional **Stance** setting provides increased immediate resistance at loading response for increased stability and confidence
- Optional **Swing Initiation** setting:
  - Knee remains stiff when swing initiation is not activated
  - Keeps the knee stable in stance when lifted of the ground at less than 5° flexion
  - Increases users feeling of safety especially when taking steps in confined spaces
- New robust covers

2014 - Design Transformation

New Extension Assist

Kinematic Sensor (Gyroscope)

Increased Battery Power

Stronger Actuator

Enhanced processor, angle sensor and software

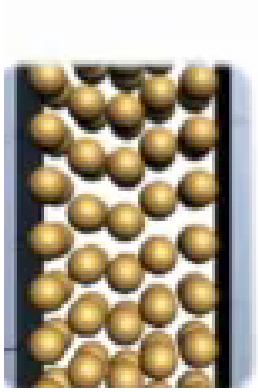
Structural Reinforcements

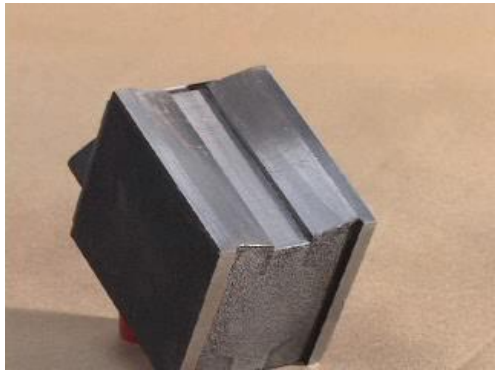
Actuator Technology: Magnetorheologic Fluid

Actuator design

- Immediate and proportional response to gait and loading changes
- Increased maximum torque for additional support and stability
- Easy swing initiation and natural swing motion (zero pressure, low-drag) actuator

Magnetorheologic technology





Magnetorheologic Fluid + AI= Comfort and Efficiency

- Initial Automatic programming (Set-up Mode)- Only 30 steps
- Long-term continuous monitoring & adaptation to changes in gait (Software design: set targets → match targets)
- Result: Enhanced and efficient walking comfort and efficiency

Weatherproof Design for RHEO KNEE and XC

RHEO KNEE and RHEO KNEE XC are rated: IP34

- **3:** Protected from solid objects greater than 2.5mm
- **4:** Water splashing against the enclosure from any direction shall have no harmful effect

- Possible scenarios:
  Condensing environments, ambient humidity and fog, spilling water, splashing water and heavy rain

Extension assist enhancements

- Faster extension rate
- Promotes heel rise and toe clearance
- Enhances perceived safety
- Lowers energy consumption / exertion
- Assists in running for RHEO KNEE XC

The fine-tuned dynamic spring release mechanism results in faster swing extension during level ground walking and stair and ramp descent activities.

In house, clinical tests show that users walk farther, faster and feel less exhausted after performing tasks.

RHEO KNEE® XC

RHEO KNEE **XC** offers increased functionality for the more demanding prosthetic user without compromising RHEO KNEE's unique combination of stability and dynamics.

Featuring a weatherproof design, **stair ascent**, **running** and **automatic cycling recognition**. RHEO KNEE XC is the affordable microprocessor-controlled prosthetic knee for the more demanding prosthetic user.

Stair Ascent Mode: step-over-step

Requires:

- >25° knee flexion and loading to engage mode
- Activates swing extension stop at 25° flexion
- Prevents hitting next step and pre-positions foot for loading

Stair Ascent strategies:

- Prosthetic side first
- Sound side first

Training is needed to achieve proficiency:

- Rhythm / timing
- Posture
- Loading the prosthesis
- Hip extension & flexion control
- Confidence

Stair Ascent Mode: step-over-step
Sound side first

Results: Stair Quality Index

The Stair Quality Index improved when using the RHEO KNEE XC ascending stairs. The improvements measured when ascending stairs are statistically significant (*).

Baseline	Own prosthesis	5,69
3 weeks	RHEO KNEE XC	8,75*

RHEO KNEE XC allows for step over step stair climbing with easy, smooth transitioning into and out from the stair cases.

Advanced actuator and resistance control ensure best possible resistance in all activities, including stairs.

Genium users that did not use the stair ascent feature on a daily basis where able to use the stair ascent with the RHEO KNEE XC. **It was easier to trigger the stair mode.** Being quicker and easier to learn increases the potential to actually use the feature.

Automatic Cycling Recognition

- New improved cycling recognition using gyro signal with lower threshold
- Cycling is recognised even at slow cadence improving usability

Enter the cycling mode:

- 2 rotations with minimum load on the knee
- One long beep confrmation

The knee moves freely with no resistance during cycling mode supporting a wide range of cadence and activity levels and efficient power transfer to the pedals.

- Exit the cycling mode:
  - Extending the knee to 15 degrees of flexion or less: one short beep
- Correct saddle/pedal height: The knee should not fully extend during pedaling

Running Mode

The RHEO KNEE **XC** has been designed and tested for intermittent running, typical in the everyday active life.

- User weight <110 kg
- Activates when stance time is < 0.3s
- Automatic – no mode switching required
- During running: the stair ascent step-over-step is blocked.
- Tested at speeds up to 12.6 km/h
- Recommended feet:
  - Re-Flex Shock
  - Re-Flex Rotate
  - Pro-Flex XC
  - Pro-Flex XC Torsion

New RHEO KNEE Features

- **Robust covers**
  - New cover design with improved robustness
  - Secure and comfortable kneeling
  - Easy access to charging port

- **Enhanced stability control**
  - Special focus on increased stability for insecure users
  - More secure and consistent swing initiation
  - Easier knee extension from squatting
  - Improved Automatic Cycling Recognition at slow cadence

- **Functional training app**
  - Interactive functional training module in Össur Logic
  - Fundamental exercises to help users get the most out of the RHEO KNEE and RHEO KNEE **XC**

New Covers for RHEO KNEE and RHEO KNEE® XC

Single front panel mechanically fastened to frame

Wider thicker knee pad for support when kneeling in a 45° abduction angle

Knee Centre Indicator

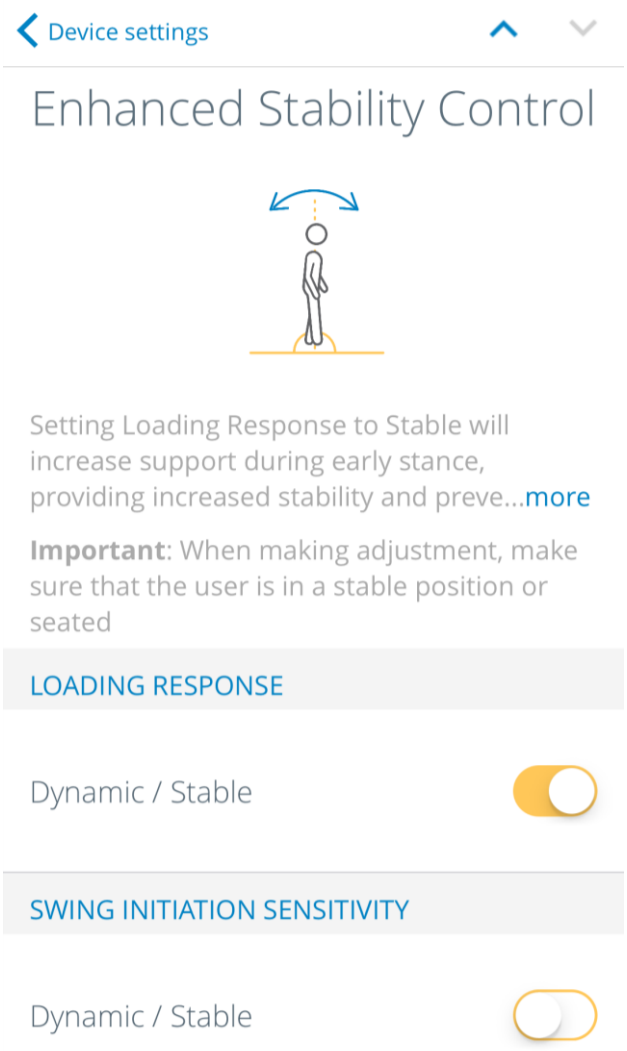
Easier access to charge port

Easier actuation of on/off switch with fingers

Enhanced stabilty control - Overview

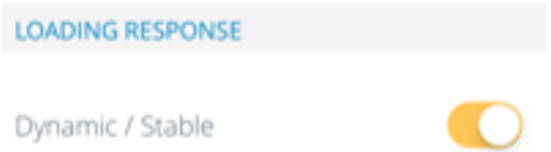
Enhanced stability control: 2 optional settings

- Purpose: Provision of consistent stance support, safety and predictability
- Adjusts loading response and swing initiation sensitivity on ÖSSUR LOGIC
- Selecting stable will sacrifice some of the free swinging dynamics for increased stability
- Stable options are aimed at insecure, lower active users or primary users
- Can be used as a transitional setting in early rehab



Loading Response: Stable Setting

- The RHEO KNEE will provide fixed amount of resistance at loading response as opposed to the standard angular velocity dependent resistance
- **Stable Setting:** Resistance ramps to 50% of maximum, providing immediate high resistance which is not dependent on proportional load.
- Increases support and confidence with minimal loading of prosthesis
- Eliminates unwanted stance flexion
- Provides increased resistance when yielding down shallow ramps
- Useful for users that prefer ‘step-to’ gait pattern
- **Dynamic Setting** is the default RHEO KNEE behavior

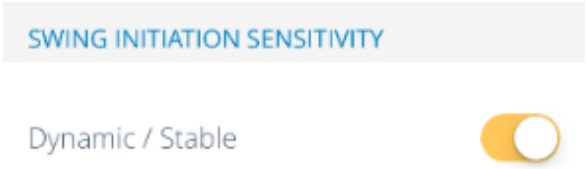


Loading Response Application

- Primary users
- Users with significant co-morbidities:
  - K2 classified amputees
  - Ipsilateral Upper limb involvement
  - Bi-lateral
  - Neurological condition
- Fundamental weight-bearing training
- Users with weakness of the core and residuum who have difficulty with required loading on dynamic setting
- Ramp descent training
- Negotiating uneven ground and surface transitions (e.g. walking on concrete to grass - despite the softer grass surface the user will notice the increased resistance at loading response)

Swing Initiation: Stable Setting

- Prevents knee swing flexion outside of typical ambulation pattern
- **Stable Setting:** When prosthesis is lifted off the ground with <5° flexion the knee remains in stance (remains stiff)
- Useful for lower active users who prefer a stiff-leg ambulation pattern when taking small steps (e.g. confined spaces – kitchen, bathroom)
- Stance to swing is not triggered accidently for example when turning with RHEO KNEE on inside leg
- Heel to toe roll-over required to initiate swing – otherwise remains in stance
- Temporary transition tool for insecure users during initial fitting/rehab



Swing Initiation Sensitivity Application

Dynamic

Stable

Other RHEO KNEE and RHEO KNEE XC Improvements

- **More consistent detection of swing initiation**
  - Shank rotation range added as a prerequisite for transitioning to pre-swing
  - Provide more consistent support during stance as swing is not triggered accidently

- **Easy knee extension from a squat position**
  - RHEO KNEE detects extension from a high flexion angle and lowers extension damping value
  - Allows for more contribution of the prosthetic side saving the sound side

- **Improved Automatic Cycling Recognition (RHEO KNEE XC only)**
  - Using gyro signal with lower threshold;
  - Cycling is recognised even at slow cadence improving usability

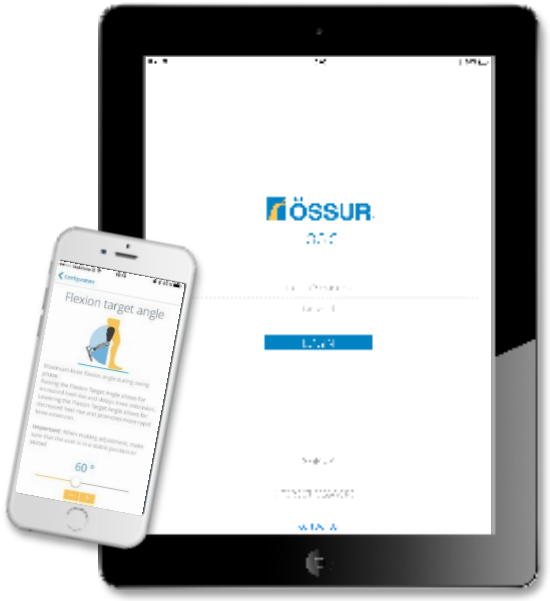
ÖSSUR LOGIC – User mode

RHEO KNEE users can download the Össur Logic app from the Apple App Store free of charge and access the user mode.

The RHEO KNEE communicates with iOS devices (iPhone/iPad/iPod Touch) and provides the end user with valuable information without allowing any control over the prosthetic device.

The user mode includes the following functionality:

- Battery status
- Charging status
- Step count
- Functional Training Exercises
- User preferences including:
  - Sounds and/or vibration
  - **Extension hold**
- User information
- Instructions for use (link)
- Firmware version
- Alarms and alerts (link)



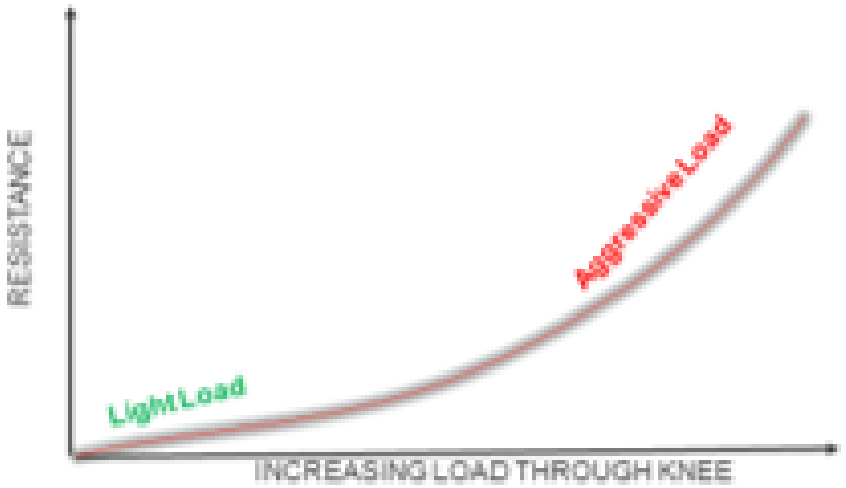
Benefits of RHEO KNEE and RHEO KNEE XC:

- Weight Activated Stability with optional **Enhanced Stability Control**
- Knee accommodates changes in walking velocity
- Smooth transitions between phases of gait
- Potential with **Pro-Flex** and training to decrease stresses on the remaining limb

RHEO KNEE and XC features Dynamic and Stable options for Loading Response

Weight Activated System:

- Stance resistance responds proportionally to load
- Body posture can influence the response



Enhanced Stability Control:

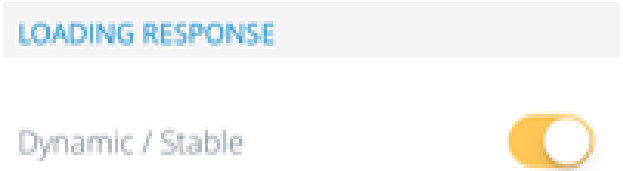
- Consistent resistance at loading response
- More consistent swing initiation, adding security
- Knee remains stiff if swing is not triggered

Other improvements:

- Easier knee extension from squatting
- Improved Automatic Cycling Recognition at slow cadence (XC only)

Applications for Enhanced Stability Control:

- Transitional setting for primary user.
- Older or less stable amputees requiring increased feeling of safety.
- Significant co-morbidities
  - e.g. K2 classified amputees.
  - Ipsilateral Upper limb involvement
  - Bi-lateral
  - Neurological conditions



- Amputees with weakness of the core and residuum who have difficulty with required loading on dynamic setting.

Gait is Optimised By: Reaching full Toe Off and End of Range Hip Extension.

1. The full length toe lever results in a longer stance phase which initiates an extension moment in the knee, resulting in a smooth **transition from stance to swing.**

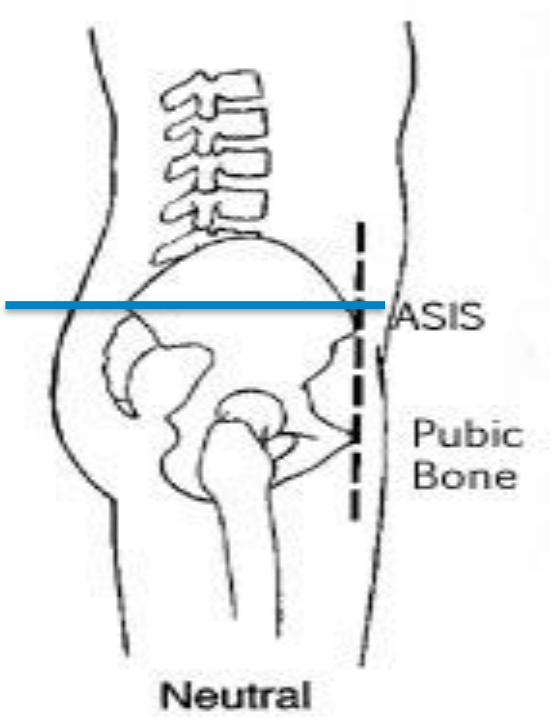
2. Combined with a Flex-Foot there is a smoother transition onto the intact leg, **decreasing the stresses on the remaining limb**.

3. Resulting in a **more symmetrical gait.**

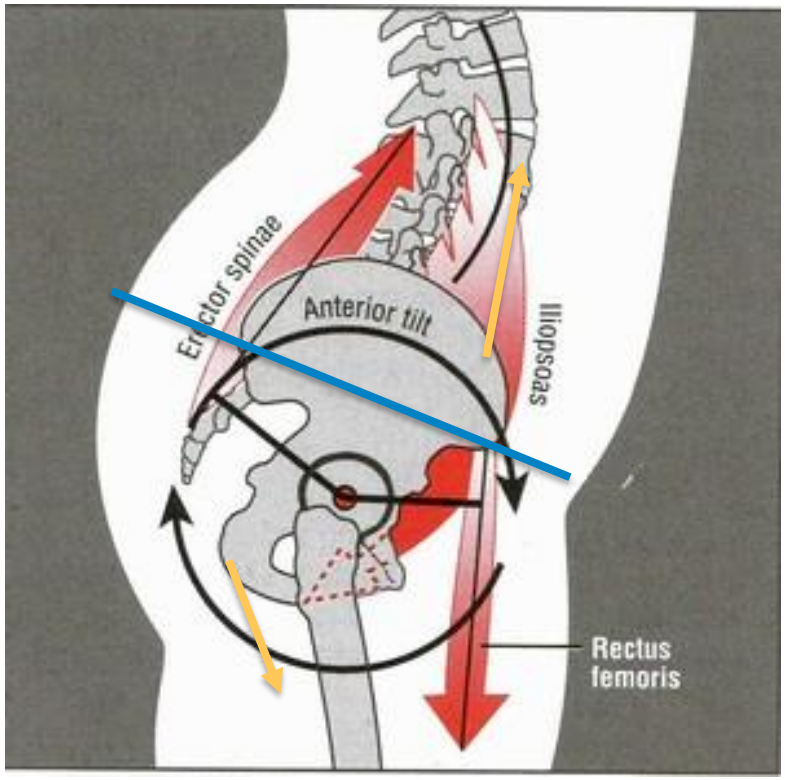
4. **Essential to initiate swing when ESC is activated.**

Amputation affects core stability of the T/F amputee by decreasing the ability to stabilise the pelvis in prosthetic stance phase in the AP plane.

Pre Amputation



After T/F amputation



The Effect of Poor Core Stability on T/F Gait and use of RHEO KNEE

Predisposition to Anterior pelvic tilt (sagittal plane) and hip flexion

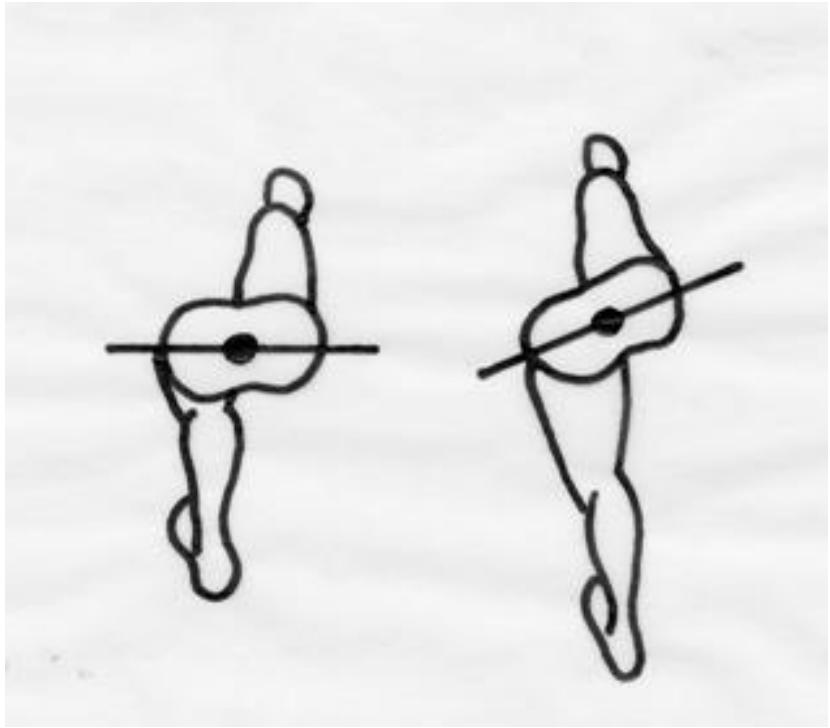
- T/F ↓ stabilisation of pelvis by hamstrings
- Tight/overactive psoas
- Weakened/lengthened abdominals
- Imbalance in strength between sides of abdominal musculature
- Weakened/lengthened gluteals

Consequences for T/F Gait

- ↓ Push off by the Hip extensors
- Shortened intact leg step length
- Difficulty initiating and clearing prosthesis during swing phase
- May lead to shortening of the prosthesis. Predisposes to other Gait deviations/problems
- Impaired momentum and loss of power

Pelvic movements during Gait that may reflect a decrease in Core Stability

Pelvic Rotation in Transverse Plane

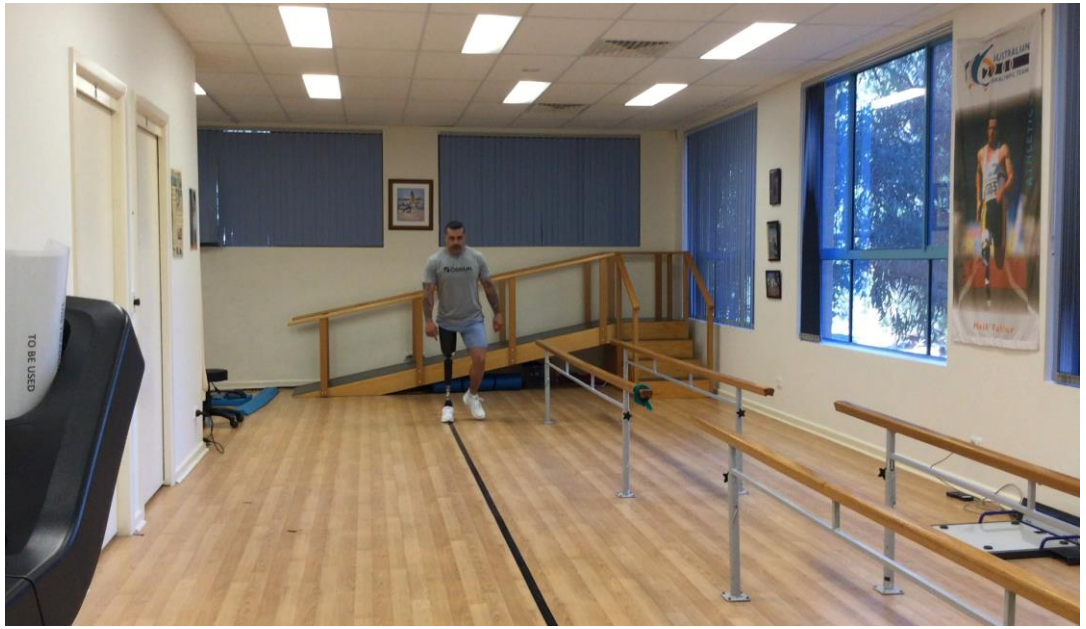


Excessive Posterior Rotation at End of Prosthetic Stance:

- Weakened End of Prosthetic Stance.
- Decreased push off from prosthetic toe.
- May also be associated with External Rotation of the foot.
- Avoidance of the provided toe lever = impaired momentum.

Consequences of too much hip flexion and/or not achieving proper Toe-Off

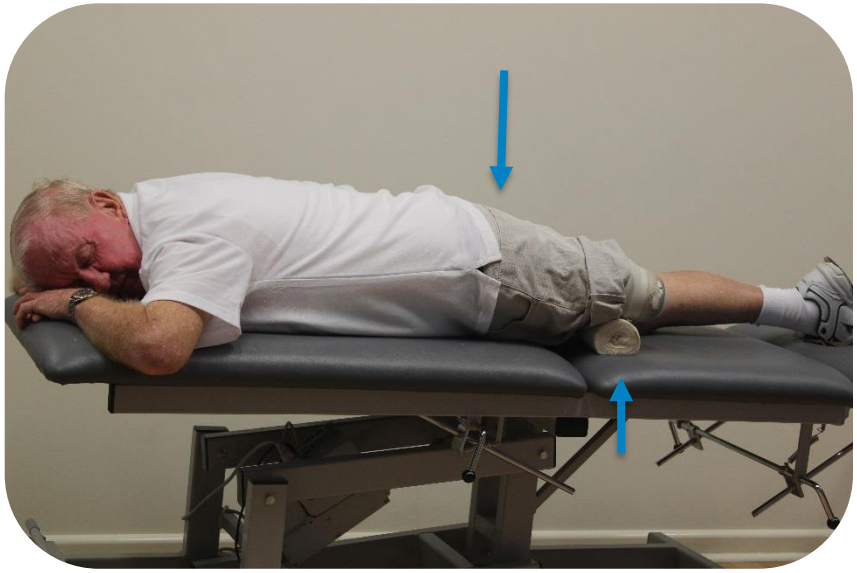
- Shortened stride with sound limb
- Shortened toe lever
- Difficulty initiating prosthetic swing
- Catching prosthetic foot and falling



Prevention of Hip Flexor Complications in Amputee Gait:

- Hip flexor stretches
- Strengthening of the Extensors with associated core activation to prevent pelvic rotation
- Incorporation into the gait pattern

Adequate Hip ROM and Strength Throughout Available Range



- Daily for 20 minutes
- Add extension exercises whilst pushing the ASIS into the bed
- Do not allow the pelvis to come off the bed

- Strengthening Extensors

Gaining Confidence in Weight Activated Resistance

- “Testing” the knee in initial training

- Strengthening the core and hip muscles on the loaded RHEO

Stability on RHEO KNEE is Optimised By:

- Effective Weight bearing
- Lateral Pelvic Shift
- Controlling the location of weight bearing along the length of the foot
- Good for transition to gym training for K3-4 levels

Safety provided with RHEO: Training use of Stance Resistance

- Sitting and Squatting Drills
- Emphasis on weight bearing through the heel of the prosthesis
- Core Stability and gluteal activation are important to maintain neutral lumbar spine and pelvic position and ensures that the prosthetic knee does not translate forward in space

Resisted Walking Drills:

- Resisting lateral pelvic shift

- Resisted backwards walking emphasises pushing into RHEO KNEE stance resistance

Stair Descent

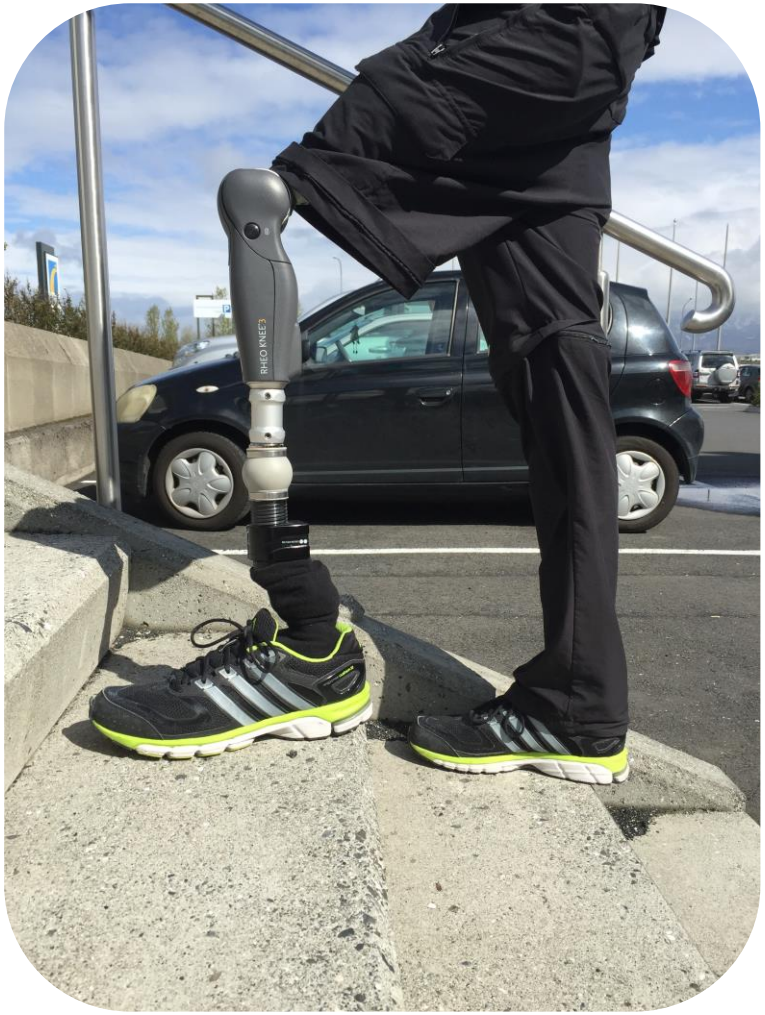
Combination of the **RHEO KNEE** and **Pro-Flex** allows the user to leave more of the foot on the step.

Progressing Up Stairs

- Do not allow the knee joint to translate forwards
- Push down and back with the stump
- It can be easier to initate prosthetic step up with the sound foot on the first step

At the top of the Stairs:

- Continue, it is easier to stay in rhythm
- **Last step to level ground:**
  - Prosthetic foot first
  - Extend residual limb
  - Roll over the prosthetic foot
  - Small step with the sound side
  - Continue walking
- **Sound foot first**
  - Initiate hip flexion with the residual limb: The RHEO KNEE XC keeps the knee flexion longer in position
  - Wait a split second so the RHEO KNEE XC will exit stair mode
  - Continue walking



Training on Slopes

- Avoid overstepping.
- Load the prosthesis and “ride” it down. Avoid extending the stump.
- Maintain an erect trunk.
- Consider stable setting for initial rehab for increased confidence and safety

ÖSSUR LOGIC In App Functional Training Excersies

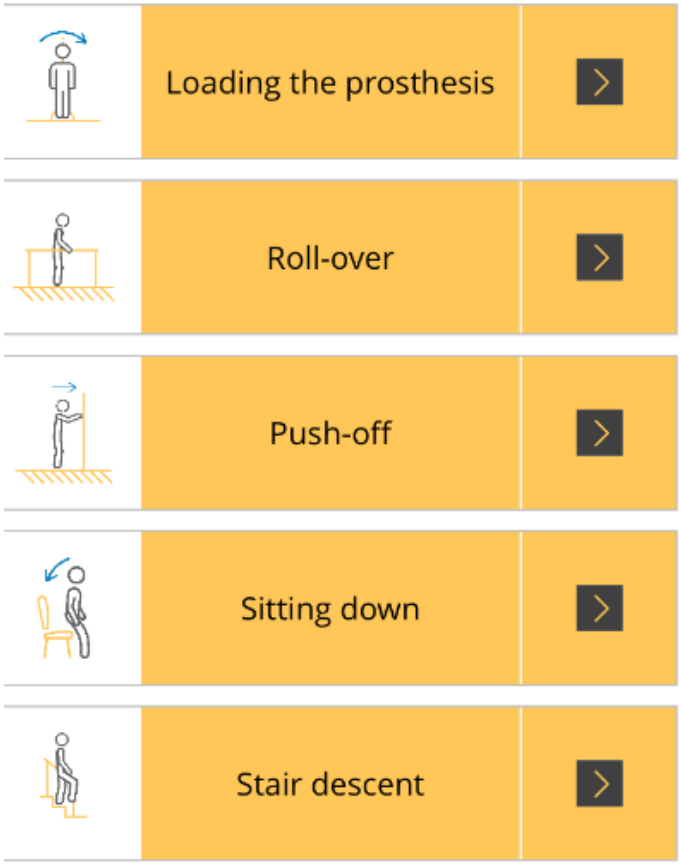
Össur is developing an App to make functional training accessible for users

Functional training app:

- Develops fundamental skills for mobility progression
- Increase user confidence
- Accessible to users via the user app

Includes:

- Training with instructions
- Videos
- Visual/audible feedback on execution of exercise

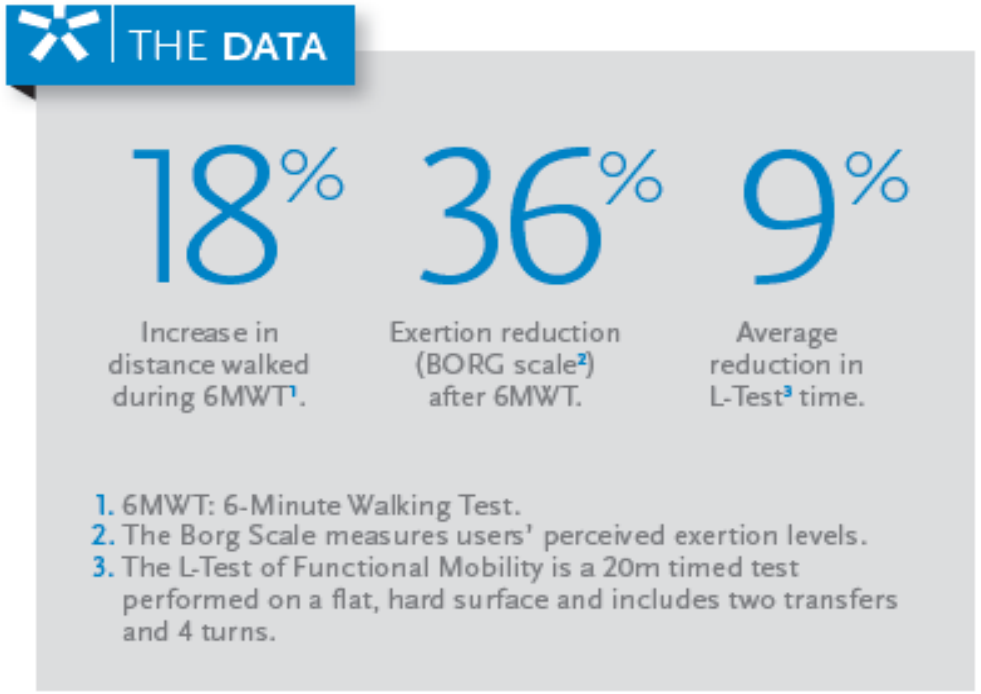


Improved Clinical Outcomes

- Internal Össur Medical Office study

- 13 unilateral transfemoral users:
  - 3 RHEO KNEE 2 users
  - 6 original RHEO KNEE 3 users
  - 4 hydraulic MPK users (1 Cleg 4, 2 Genium, 1 X3)

- K3 – K4 population:
  - Age: Average 42 Years (29-68)
  - Weight: Average 82kg (57-104)



- **Comparison of existing knee to RHEO KNEE XC (after 3 weeks of use)**

6 Minute Walk Test (6MWT)

- 6 minute walk test was performed by each participant in the study using their own microprocessor knee as a baseline, then compared to the RHEO after 3 weeks use
- The walking distance during 6MWT increased on average for all users when using the new RHEO KNEE design. The improvements measured are statistically significant

Baseline	Own prosthesis	428,23m
3 weeks	New RHEO KNEE	506,00m*

The results related to this test can be attributed to the nature of the RHEO actuator technology and a faster swing extension than in the previous models.

- According to literature, the following performance levels during 6MWT have been described:
- The 6MWT performance of K4 Level amputees is 419.76m
- The 6MWT performance of active duty soldiers with transfemoral amputation is 542m +/- 67 [5]

- **With RHEO KNEE XC, K4 users in the trial stepped up to another performance level which is within the range of active duty service members of the US army.**

The Borg Scale

- **The Borg Scale:** Self reported, The Borg Scale CR 10 [6] of Perceived Exertion aims to gauge how a user perceives his exertion levels. Using a scale from 0 to 10, users grade their feeling of exertion during an exercise.

- The Borg Scale test was taken by each user before and after the 6MWT to measure the difference in exhaustion before and after exericise. The same sequence was repeated on the new RHEO KNEE once users had had 3 weeks experience using the new knee.

Baseline	Own prosthesis	3,04
3 weeks	New RHEO KNEE	1,93

- **When using the new RHEO KNEE, users reported less exhaustion than they did when using their own prosthesis. At the same time they walked longer distances**

- **The new RHEO KNEE reduces the perceived exertion and thereby allows for walking longer distances.**

L-Test and PEQ MS 12/5

- **The L-Test:** Consists of ambulation over 20 meters and includes two transfers and 4 turns. It is a timed event from when the user rises from the chair to returning to a seated position, walking at their self selected speed. [7]

- The time required to complete the 20m L-test decreased when using the new RHEO KNEE design when compared to their previous MPK . The improvements measured are statistically significant:

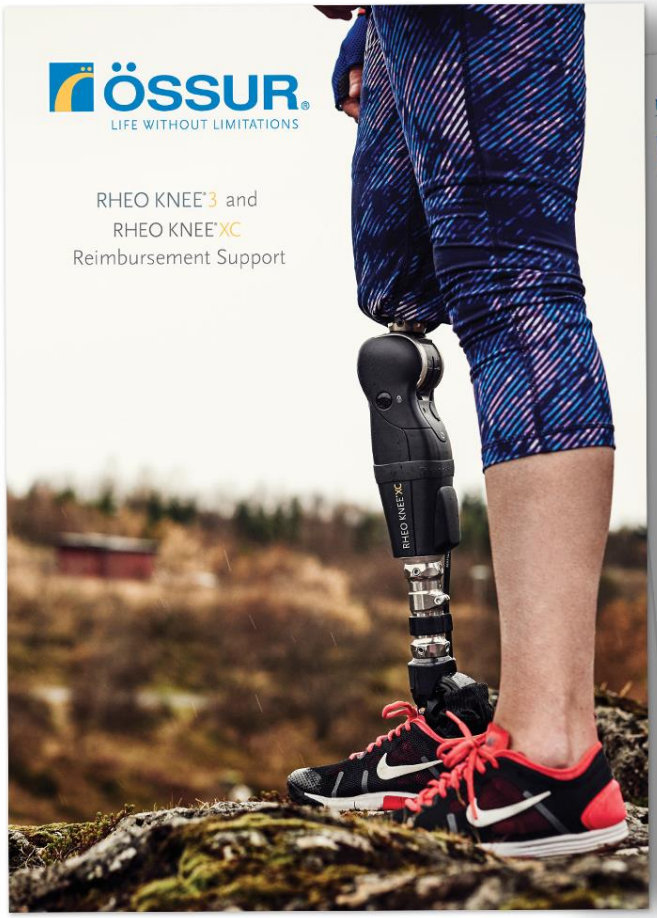
Baseline	Own prosthesis	21,46 sec
3 weeks	New RHEO KNEE	19,46 sec*

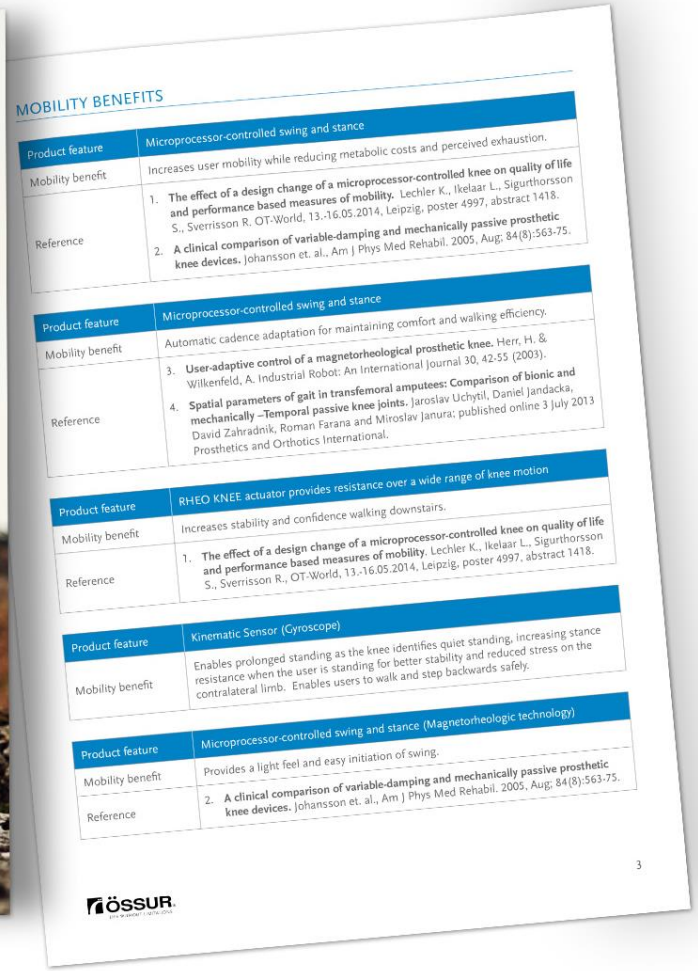
- **PEQ MS 12/5:** Self administered questionnaire, aimed to evaluate prosthetic function and prosthetic related changes to quality of life. The evaluation gives results on the scale of 0-4.

Baseline	Own prosthesis	3,07
3 weeks	RHEO KNEE XC	3,59*

The improvement with the RHEO KNEE were statistically significant with users grading their prosthetic device and their quality of life higher when using the RHEO KNEE XC than other MPK devices

Reimbursement Support Document: RHEO KNEE and RHEO KNEE® XC





MOBILITY BENEFITS

Product feature	Microprocessor-controlled swing and stance
Mobility benefit	Increases user mobility while reducing metabolic costs and perceived exhaustion.
Reference	1. **The effect of a design change of a microprocessor-controlled knee on quality of life and performance based measures of mobility.** Lechler K., Ikelaar L., Sigurthorsson S., Sverrisson R. OT-World, 13.-16.05.2014, Leipzig, poster 4997, abstract 1418. 2. **A clinical comparison of variable-damping and mechanically passive prosthetic knee devices.** Johansson et. al., Am J Phys Med Rehabil. 2005, Aug; 84(8):563-75.

Product feature	Microprocessor-controlled swing and stance
Mobility benefit	Automatic cadence adaptation for maintaining comfort and walking efficiency.
Reference	3. **User-adaptive control of a magnetorheological prosthetic knee.** Herr, H. & Wilkenfeld, A. Industrial Robot: An International Journal 30, 42-55 (2003). 4. **Spatial parameters of gait in transfemoral amputees: Comparison of bionic and mechanically –Temporal passive knee joints.** Jaroslav Uchytil, Daniel Jandacka, David Zahradnik, Roman Farana and Miroslav Janura; published online 3 July 2013 Prosthetics and Orthotics International.

Product feature	RHEO KNEE actuator provides resistance over a wide range of knee motion
Mobility benefit	Increases stability and confidence walking downstairs.
Reference	1. **The effect of a design change of a microprocessor-controlled knee on quality of life and performance based measures of mobility.** Lechler K., Ikelaar L., Sigurthorsson S., Sverrisson R., OT-World, 13.-16.05.2014, Leipzig, poster 4997, abstract 1418.

Product feature	Kinematic Sensor (Gyroscope)
Mobility benefit	Enables prolonged standing as the knee identifies quiet standing, increasing stance resistance when the user is standing for better stability and reduced stress on the contralateral limb. Enables users to walk and step backwards safely.

Product feature	Microprocessor-controlled swing and stance (Magnetorheologic technology)
Mobility benefit	Provides a light feel and easy initiation of swing.
Reference	2. **A clinical comparison of variable-damping and mechanically passive prosthetic knee devices.** Johansson et. al., Am J Phys Med Rehabil. 2005, Aug; 84(8):563-75.

3

Overview of Mechanical knees

Locking Knee

Balance Knee OM8

Balance Knee OFM2

Balance Knee OFM1

OP2 Knee

OP4 Knee

Paso Knee

OH7 Knee

OH5 Knee

OHP3 Knee

OP5 Knee

Mechanical Knee Prescription Guideline

ÖSSUR
LIFE WITHOUT LIMITATIONS

Mechanical Knee
Prescription Guide

PASO KNEE™

The PASO Knee features an innovative autoadaptive pneumatic swing phase control which requires no valve adjustments. The knee will automatically respond to any change in cadence up to 7km/hr with no adjustments required from the prosthetist. The PASO Knee is suitable for a wide range of users due to its stability and responsiveness.

Unique 'closing geometry' creates an inherently more stable system during stance than a standard 4-bar design. It ensures optimal stance phase stability from loading response through terminal stance until weight is applied on the toe in conjunction with a hip flexion moment to release the knee.

Unique Features

- Low proximal build height ideal for long residual limbs and knee disarticulation users
- Auto-adaptive pneumatic swing phase control adapts automatically
- Closing geometry (refer to page 22)
- Choice of 4 socket connection options, providing a variety of shift, rotation, tilt and stance flexion adjustments

TECHNICAL SPECIFICATION

WEIGHT LIMIT
- 136kg

WEIGHT
- 1050g

EFFECTIVE BUILD
- 158mm

KNEE FLEXION
- 150°

SWING CONTROL
- Auto-adaptive Pneumatic

STANCE CONTROL
- 4-Bar Closing Geometry (↑ Stability) - adjustable

MOBILITY GOALS AND REQUIREMENTS

- Requires enhanced knee stability beyond basic 4-bar during early stance
- Ability or potential for moderate - high cadence variation
- Regularly traversing different terrain: level and uneven ground, shallow slopes
- Higher loading or impact requirements

RECOMMENDED FEET

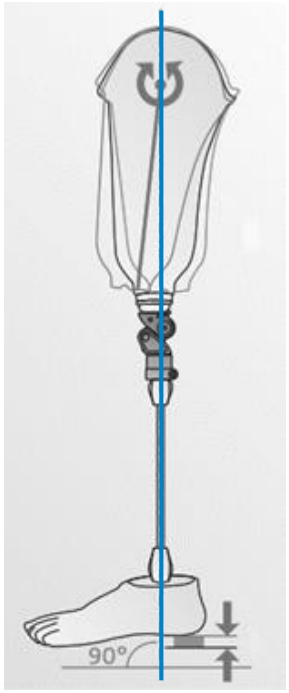
Part #	Description
1728180	PASO Knee with pyramid adapter
1728181	PASO Knee with IKF adapter
1728182	PASO Knee with loop adapter
1728183	PASO Knee with 3-arm adapter

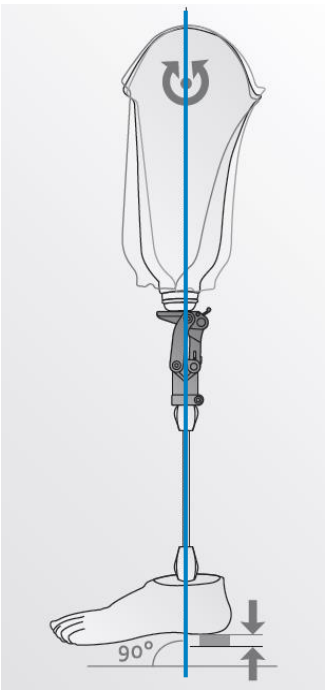
K2 - K4 ACTIVITY LEVEL 11 ÖSSUR

Alignment reccomendation

Monocentric

- Alignment reference line from bisection of socket on ischial level should pass 5 – 15 mm anterior to the pivot axis of the knee and the posterior 1/3 of the foot





Polycentric

- Alignment reference line from bisection of socket on ischial level should pass through the pivot axis of the knee and the posterior 1/3 of the foot

- Pivot axis is the most proximal anterior axis

Choice of 4 Proximal adapters

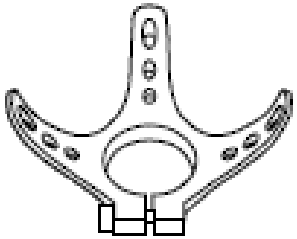
The following knees have 4 options for proximal adapters: Balance Knee OFM1, OP5 Knee, OHP3 Knee, OH5 Knee, OH7 Knee, PASO Knee

Male pyramid:

- 5mm AP/ML shift
- 360° rotation possible

3-prong adapter:

- 5mm AP/ML shift
- 360° rotation possible

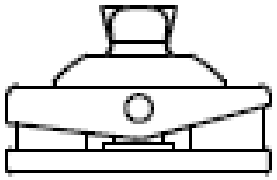


Loop adapter:

- Can tilt up to 10° using rotable discs
- 360 rotation possible

IKF adapter:

- Stance Flexion Bumpers
- Shock absorption
- No shift or rotation



Mechanical Knee Options: K1-K2

Locking Knee

- Simple locking mechanism
- Lightweight
- Durable
- Low build height

Balance Knee OFM2

- Weight Activated
- Adjustable friction
- Optional lock
- Extension spring
- Brake play screw

Balance Knee OFM1

- 4 bar design
- Adjustable axis friction
- Optional lock
- Extension spring
- Option of 4 proximal adapters

Balance Knee OM8

- 4 bar design
- Adjustable centroid for ease of set up (Adjustable stance release)
- Adjustable axis friction
- Extension spring
- Weight rating to 136kg

Mechanical Knee Options: K2-K3 (Pneumatic)

OP4

- Weight activated
- Adjustable brake sensitivity
- Pneumatic cylinder
- Flexion and Extension set independently
- Slim design

OP2

- 4 bar design
- Adjustable centroid-(Adjustable stance release)
- Adjustable axis friction
- Pneumatic cylinder
- Flexion and Extension set indepently

OP5

- 4 bar design
- Pneumatic cylinder
- Flexion and Extension set independently
- Choice of 4 proximal adapters ideal for KD

OHP3

- Polycentric design featuring closing geometry
- High pressure Pneumatic cylinder capable of fast walking 4+ km/hr
- Adjustable stance release (wedges)
- Choice of 4 proximal adapters ideal for KD

OHP3 Knee

- **Recommended foot solutions:**
  - Assure
  - Vari-Flex
  - Vari-Flex Modular
  - Talux

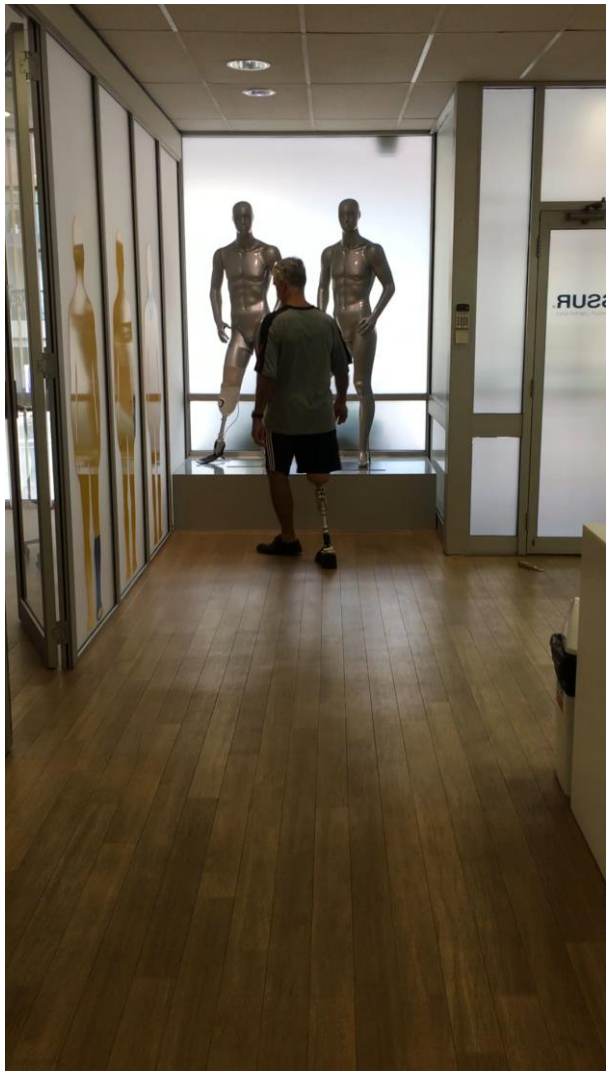
Mechanical Knees Options: K3-K4

OH5

- K3 Users
- 3 Phase Hydraulic swing
- Polycentric featuring closing geometry
- Choice of 4 proximal adapters ideal for KD or long TF

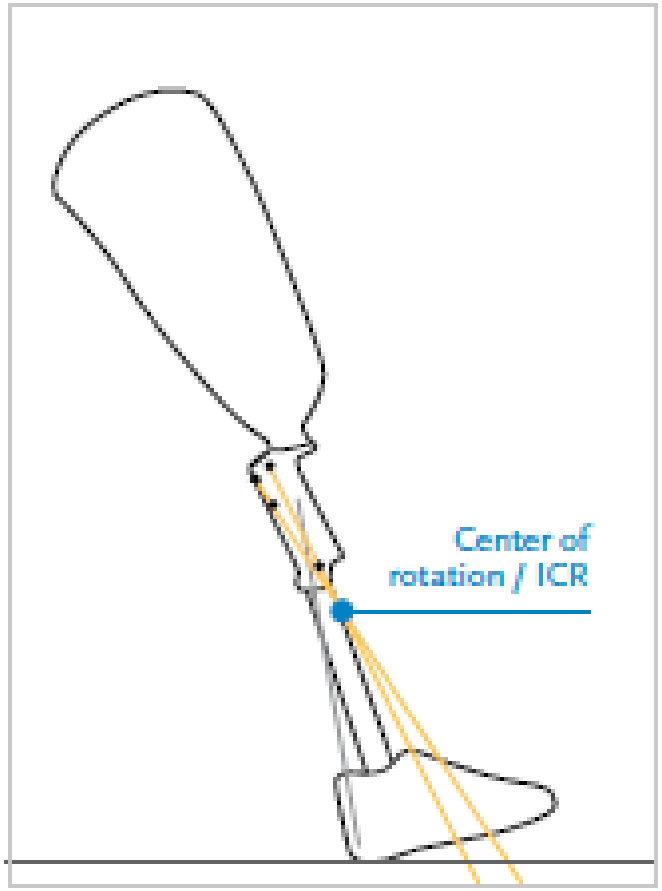
OH7

- K3-K4 Users
- 3 Phase Hydraulic swing
- Polycentric featuring closing geometry
- Choice of 4 proximal adapters ideal for KD or long TF
- Adjustable stance release with wedge
- Heavier duty knee capable of fast paced walking and running (136kg)



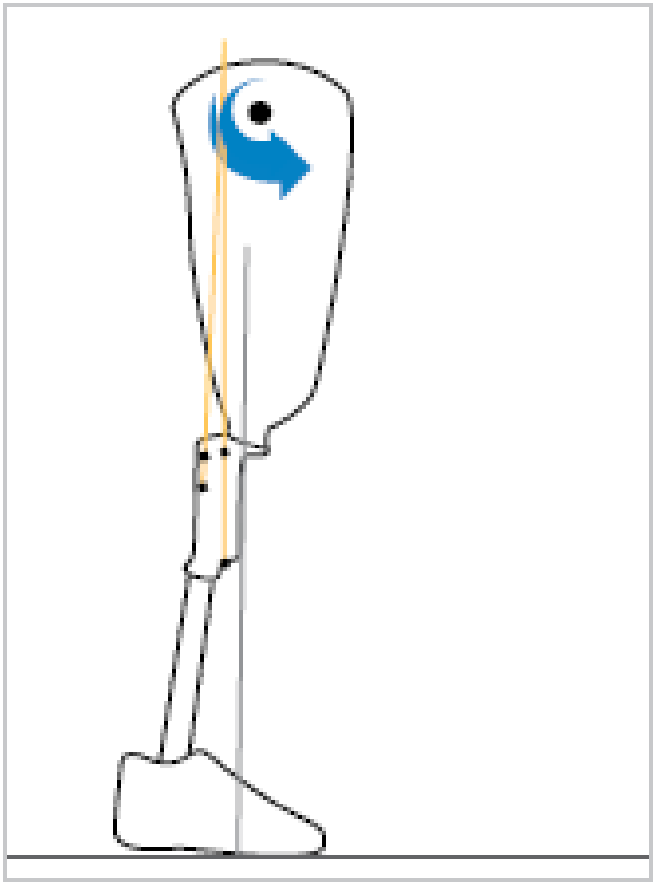
Closing geometry

Closing geometry- Initial contact



- At Initial contact the instantaneous center of rotation is in front and below the ground reaction force.
- The knee is fully extended and inherently stable even if the user creates a hip flexion moment
- Loading the knee at heel contact will push the knee into extension, increasing safety at heel contact

Closing Geometry- Midstance



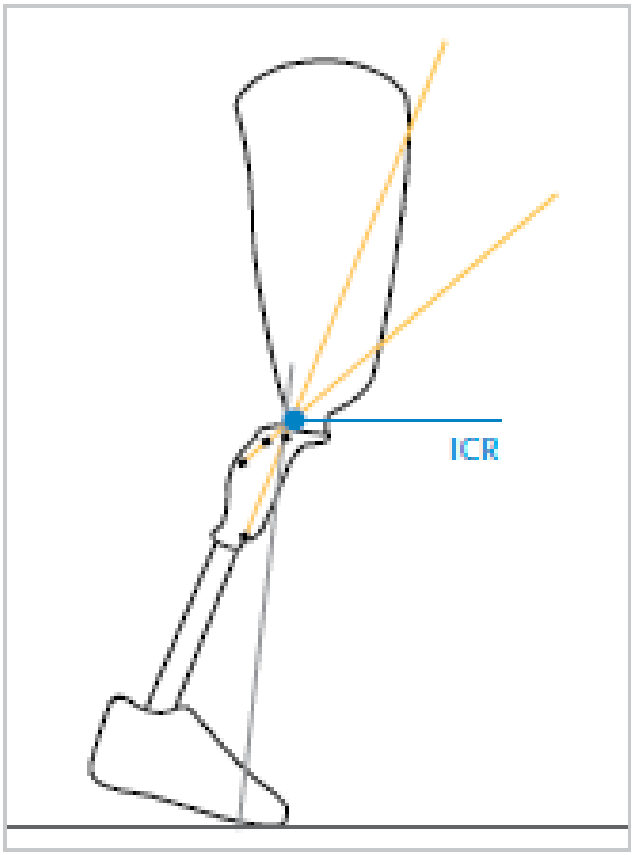
At midstance the instantaneous centre of rotation is moving through the floor due to the design of the knee axis

The front and rear bars move into a parallel position

The ICOR then moves to be proximal and posterior

The GRF is therefore still anterior to the knee, maintaining stability until the toe is loaded and a hip flexion moment is initiated

Closing Geometry-Terminal stance



Once the toe is loaded and a hip flexion moment has been initiated the GRF will move posterior to the ICOR

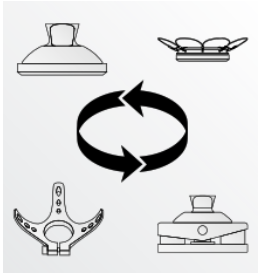
The knee will flex and allow for swing phase

This level of safety created by the closing geometery of the knee is comparable to the safety that the geometric lock provides in the Total Knee range

This safety element only works if no wedges are used in the knee. For more active individuals the knee can be made to feel more lively and release easier by using adjustment wedges

PASO Knee –Polycentric knee joint with auto-adaptive pneumatic swing phase control

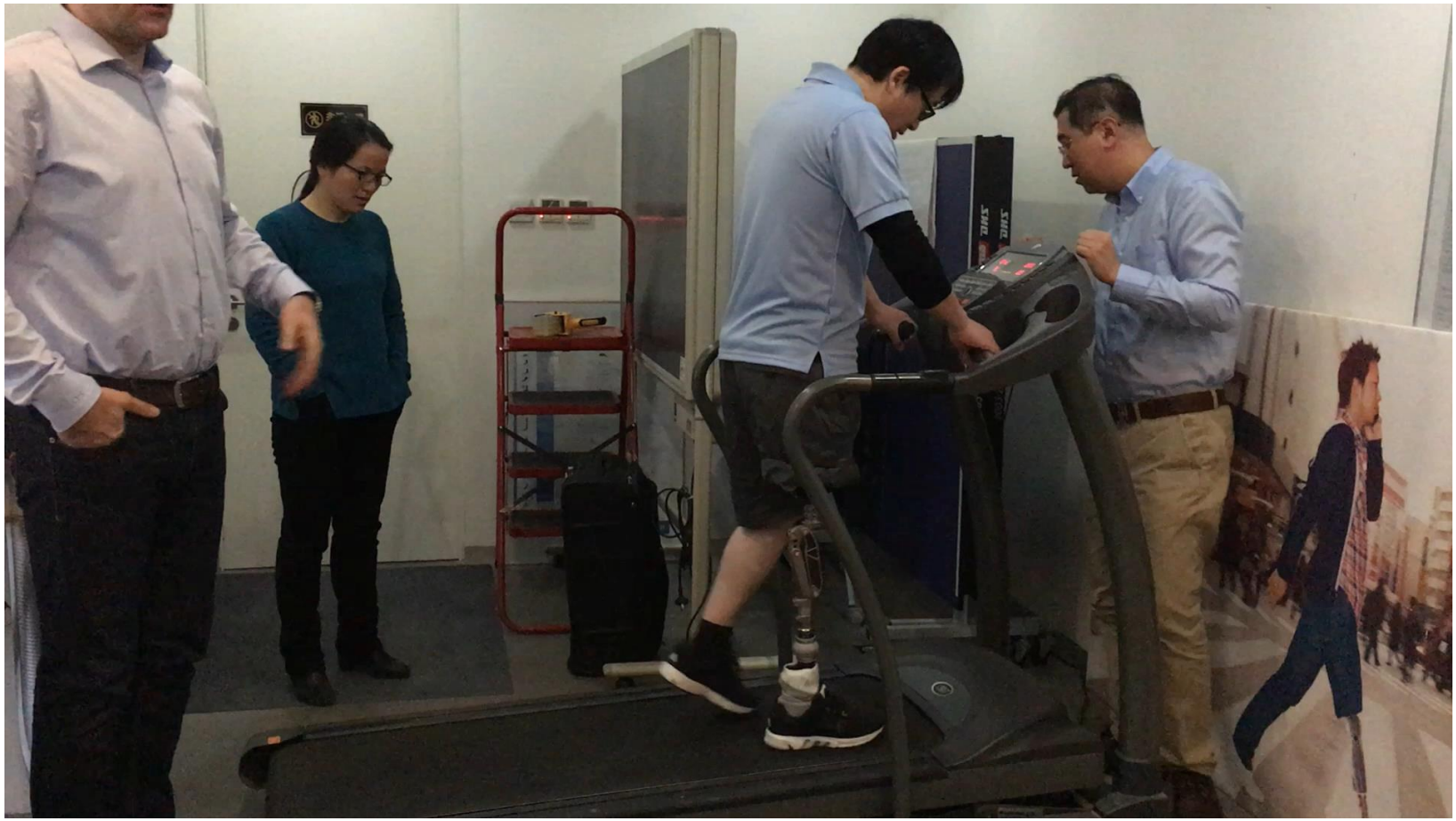
- Indications
  - Transfemoral or knee disarticulation amputation
  - K-Level 2, 3 and 4
  - Maximum user weight 136 kg



- Features **auto-adaptive swing phase control**
  - Works **‘straight out of the box’** with no adjustments required
  - Adapts to variable walking speeds (7km) and smooth and powerful running
- **Closing geometry**
  - Stance phase stability from initial contact until a hip flexion moment and toe load is initiated
- Mid swing shortening (toe clearance)
- Choice of 4 proximal adapters, for long TF and KD and IKF adapter option if stance flexion is preffered
- Adjustable geometry- wedges supplied for earlier stance release for more active users

PASO Knee – Auto-adaptive pneumatics

PASO Knee- Slow walking

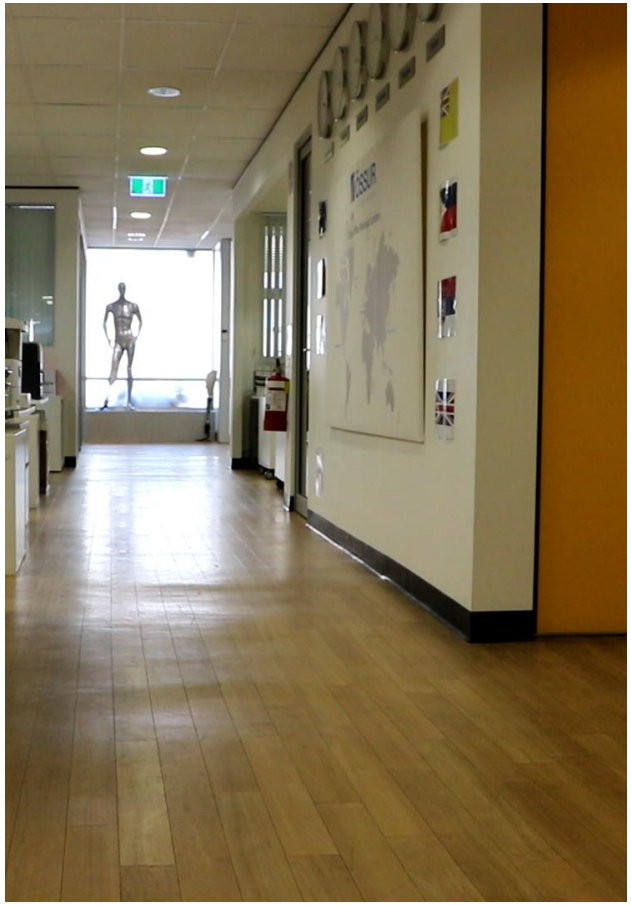


PASO Knee- 4km/hr

PASO Knee- Fast walking 7km/hr

PASO Knee- Running 12km/hr

PASO Knee- walking and running

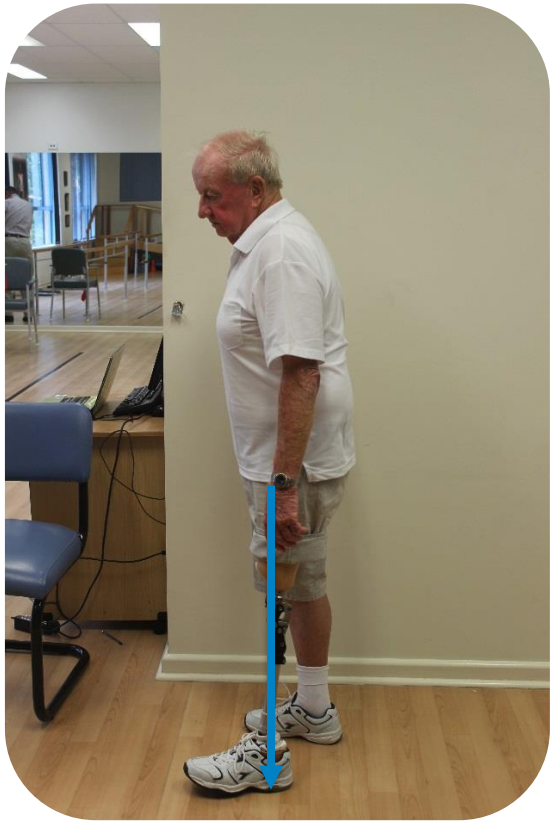


- **Recommended foot solutions**:
  - Vari-Flex
  - Vari-Flex Modular
  - Pro-Flex
  - Pro-Flex XC
  - Pro-Flex XC Torsion
  - Re-Flex Rotate
  - Re-Flex Shock

Safety needs to be trained…"The safest place for your prosthesis is underneath you."

Commonly adopted posture to avoid weight bearing produces an:

Unstable Knee and flexed hip



Reinforce correct foot placement and standing posture to produce a:

Stable knee and extended hip

Initial Gait Training using a Mechanical Knee Joint

- **Hip Extension with Core Stability**

- **Progression with resistance increases weight bearing**

Sticks too far forward encourage trunk and hip flexion

- Hip on the prosthetic side is low and posteriorly situated.
- Prosthesis is functionally lengthened.
- Difficulty breaking the knee for swing phase.
- Problems with toe clearance in swing phase.
- Patient may want the prosthesis shortened.

How the use of Aids influences Gait:

Correct stick placement

Extension of the trunk and hip encouraged

- Weight can be transferred to the front of the foot.
- Mechanical advantage is achieved to break the knee easily for swing.
- High positioning of the hip facilitates toe clearance without needing to shorten prosthesis.
- Even step length can be achieved.

Falls and Lack of Confidence in the Knee Joint occur when:

The Prosthesis is used as a “strut” and not a “leg”

- Prosthesis is placed in a position where alignment is not safe
- Prosthesis is unloaded
- Knee joints will be forced into flexion
- Excessive rotation forces around the stump

Preventing Falls when turning:

Prosthesis is used as a "leg":

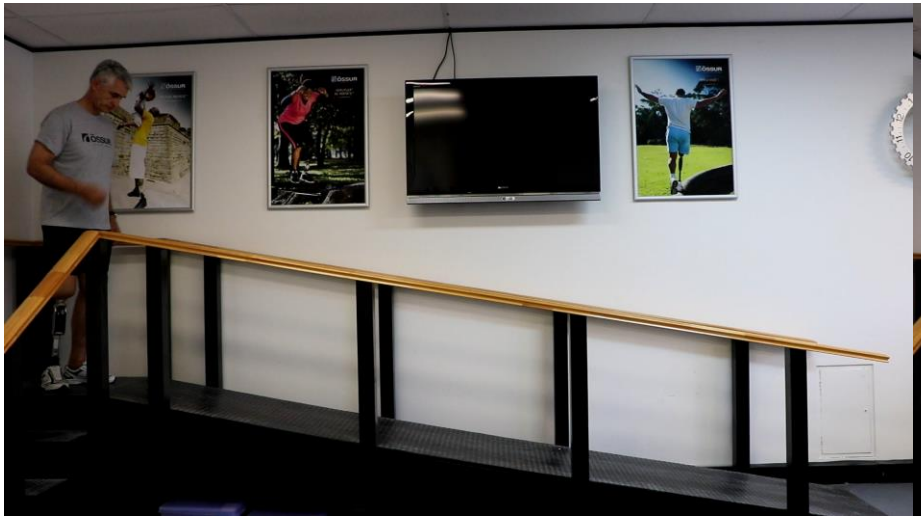
- Inherent alignment stability of the prosthesis is maximised.
- Constant reminders are needed initially to reinforce safe technique.
- Step around – never spin on the prosthesis.
- Prosthetic foot is kept under the hip.
- Prosthesis is loaded correctly.

Descent of Slopes- Mechanical Knee Joints

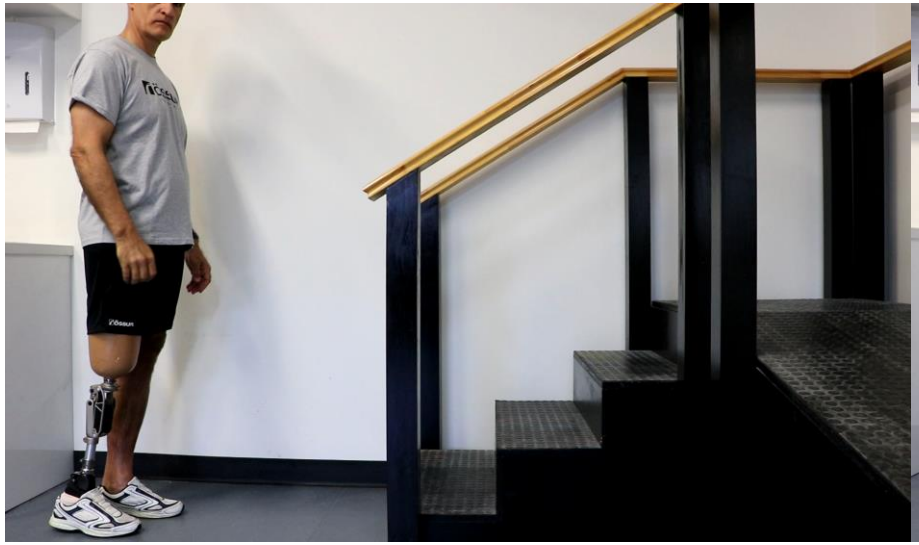
- Small step lengths
- Emphasis is on strong Hip Extension

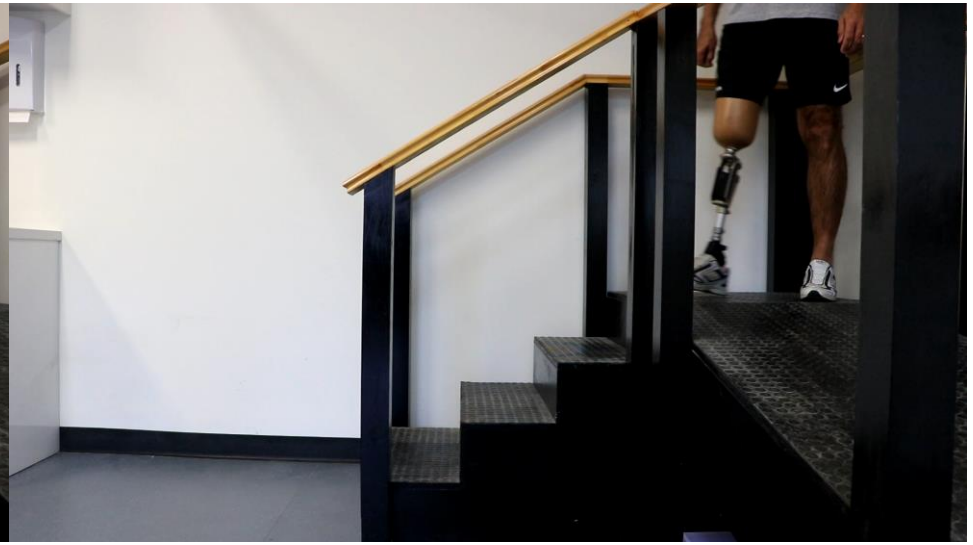
- Step to gait only
- Toes do not meet the step
- Maintain strong Hip Extension

Negotiating slopes- Mechanical Knee Joints



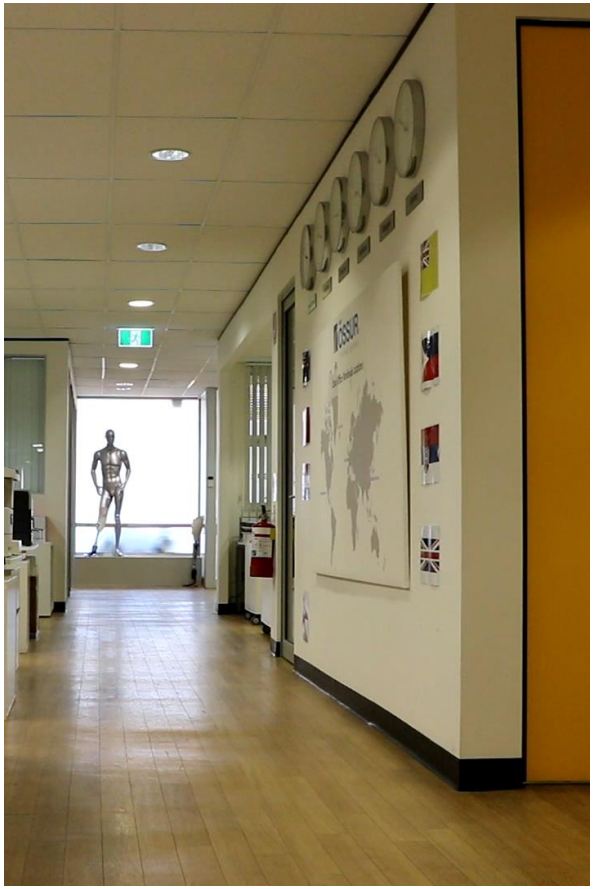
Negotiating Stairs- Mechanical knee joints



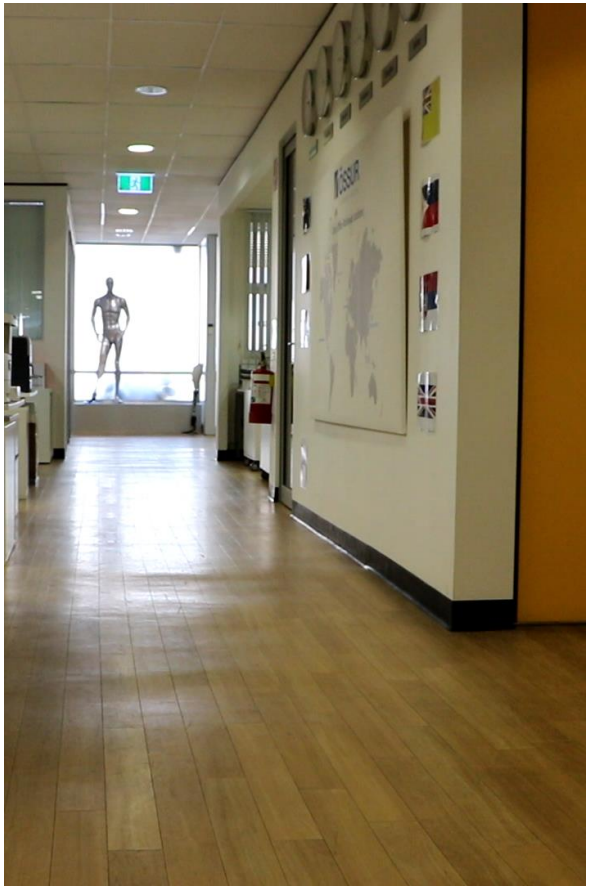


Running with the PASO Knee

Hop Skip Method



Leg over Leg Running



Prior to running, preparation of the body is key:

- Strengthening of the core
- Stability of the hips
- Maintenance of spinal alignment during prosthetic stance

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