Kinnex Summary of Evidence (Short Version)

1. Introduction

This document establishes the benefit of the Kinnex™ MPC Ankle/Foot System for persons who use a lower limb prosthesis. Evidence from 21 publications and results from a pilot study were reviewed and support benefits of the Kinnex™ over fixed ankle systems. These benefits are broken down into the following six areas: level ground ambulation, socket comfort, uneven terrain ambulation, sit to stand, ramp ambulation, and stair ambulation.

2. Benefits on Level Ground Ambulation

Medical Necessity:

Shortcomings of a fixed ankle prosthesis in replicating the functions of the anatomical ankle cause adverse effects and diminished ambulatory capacity.

- Fixed ankle prosthesis does not provide shock absorption during first rocker of stance phase[1].
- Fixed ankle prosthesis delays foot flat and leads to an unstable heel-only contact[1].
- Fixed ankle prosthesis disrupts the forward progression of the center of pressure[2].
- Fixed ankle prosthesis negatively affects weight acceptance of the amputated limb and walking speed[1].
- Fixed ankle prosthesis function does not change with walking cadence increase or decrease[3].

Benefit from Kinnex™:

The Kinnex™ provides shock absorption in loading response during the first rocker of gait through controlled hydraulic ankle plantarflexion. This leads to a more continuous center of pressure progression and a reduction in the external pressures in the prosthetic socket.

The Kinnex™ regulates ankle hydraulic resistance throughout the gait cycle in order to automatically match the necessary resistance when walking cadence is increased or decreased.

3. Benefits to Socket Comfort

Medical Necessity:

Lack of motion and angle accommodation in a fixed ankle prosthesis leads to high pressures experienced by the residual limb and leads to discomfort and skin complications.

- Users of lower limb prostheses rate socket comfort as the most important factor[4].

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[1] Perry, Jacquelin, et al. "Prosthetic weight acceptance mechanics in transtibial amputees wearing the Single Axis, Seattle Lite, and Flex Foot." *IEEE transactions on rehabilitation engineering* 5.4 (1997): 283-289.

[2] De Asha, Alan R., et al. "Attenuation of centre-of-pressure trajectory fluctuations under the prosthetic foot when using an articulating hydraulic ankle attachment compared to fixed attachment." Clinical Biomechanics 28.2 (2013): 218-224.

[3] De Asha, Alan R., et al. "Walking speed related joint kinetic alterations in trans-tibial amputees: impact of hydraulic'ankle'damping." Journal of neuroengineering and rehabilitation 10.1 (2013): 107.

[4] Legro, Marcia W., et al. "Issues of importance reported by persons with lower limb amputations and protheses." *Journal of rehabilitation research and development* 36.3 (1999): 155.

- Socket discomfort and skin complications frequently limit use of a prosthesis[5].
- Fixed ankle prosthesis exposes the limb to higher pressures on stairs, slopes [6](Wolf 2009) and uneven terrain[7].
- On level ground, the limb experiences peak stresses at the beginning and end of stance phase[6].

Benefit from Kinnex™:

The Kinnex™ accommodates up to 10° of incline slope and 20° of decline slope during ambulation through the hydraulic dampened plantarflexion and dorsiflexion in the ankle. The hydraulic resistance can be adjusted through the microprocessor software interface (app) for the Kinnex™ in order to reduce the reaction forces and pressures at the socket interface.

Supporting Evidence:

- Microprocessor ankles have been shown to reduce socket pressure during slope and stair ambulation[6].

4. **Benefits on Uneven Terrain Ambulation**

Medical Necessity: Fixed ankle prostheses are designed to support ambulation on flat level surfaces, and uneven terrain restricts mobility and balance for persons who use a lower limb prosthesis.

- Fixed ankle prosthesis causes patients to exhibit a destabilized gait pattern[8].

- Fixed ankle prosthesis on a non-flat road causes increased socket pressure[7].

Benefit from Kinnex™:

The Kinnex™ provides hydraulic controlled ankle dorsiflexion and plantarflexion to allow it to move rapidly into foot flat and accommodate the step-to-step change in slope over uneven terrain. The Kinnex™ allows patients to load the prosthesis with full body weight without losing their balance or experiencing excessive socket pressures on their residual limb.

5. **Benefits in Sit to Stand**

Medical Necessity:

Standing from a seated position is difficult for persons with a lower limb amputation using a fixed ankle prosthesis.

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[5] Gauthier-fiagnon, Christiane, Marie-Claude Grise, and Diane Potvin. "Predisposing Factors Related to Prosthetic Use by People with a Transtibial and Transfemoral Amputation." *JPO: Journal of Prosthetics and Orthotics* 10.4 (1998): 99-109.

[6] Wolf, Sebastian I., et al. "Pressure characteristics at the stump/socket interface in transtibial amputees using an adaptive prosthetic foot." Clinical Biomechanics 24.10 (2009): 860-865.

[7] Dou, Peng, et al. "Pressure distribution at the stump/socket interface in transtibial amputees during walking on stairs, slope and non-flat road." *Clinical Biomechanics* 21.10 (2006): 1067-1073.

[8] Smith, A. M. S., et al. "Prosthetic Feet with Multi-Axial Features Being Used on Uneven Terrain: A Patient-Centered Investigation." Journal of the Proceedings of the 41st Academy Annual Meeting & Scientific Symposium (2015)

- Fixed ankle prosthesis cause patients to stand with most of their weight through the sound limb[9].

Benefit from Kinnex™:

The Kinnex™ MPC Ankle/Foot System provides ankle dorsiflexion which allows patients to position their prosthesis further posterior underneath the seat. This allows patients to engage their residual limb hip and knee extensor musculature and contribute when standing from a chair.

6. **Benefits on Ramp Ambulation**

Medical Necessity:

A fixed ankle prosthesis causes compensatory movements, exposes the residual limb to excessive pressure and poses a serious environmental barrier to persons who use a lower limb prosthesis.

Slope descent
- Fixed ankle prosthesis leads to unstable heel-only support in ramp descent[1].
- Fixed ankle prosthesis increases socket pressures[6] and a knee flexion moment[10] in ramp descent.
- Fixed ankle prosthesis causes rapid knee flexion, falling forward and a short step duration and length[10].
- Fixed ankle prosthesis requires more work on sound side knee and hip in lowering the body[11].

Slope ascent
- Fixed ankle prosthesis causes knee hyperextension[11] and increased socket pressures[6] in ramp ascent.
- Fixed ankle prosthesis leads to short step length and duration along with other gait deviations in ramp ascent[12].

Benefit from Kinnex™:

Kinnex™ provides ankle plantar flexion during loading of the limb in ramp descent for an earlier foot flat with the ground, which allows the patients to lower their body while still maintaining forward momentum. The stiffness of the hydraulic dampening is optimized with the carbon fiber heel deflection by the microprocessor on every step to match the walking speed and can be programmed through the Kinnex™ microprocessor software interface (app).

Supporting Evidence:

Slope descent
- Microprocessor ankle improves walking down a slope and performing negative work through controlled plantarflexion and dorsiflexion[13].

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[9] Agrawal, Vibhor, et al. "Weight distribution symmetry during the sit-to-stand movement of unilateral transtibial amputees." *Ergonomics* 54.7 (2011): 656-664.
[10] Vickers, D.R., Palk, C.,McIntosh, A.S., Beatty, K.T., 2008. Elderly unilateral transtibial amputee gait on an inclined walkway: a biomechanical analysis. Gait Posture 27, 518–529.
[11] Fradet, Laetitia, et al. "Biomechanical analysis of ramp ambulation of transtibial amputees with an adaptive ankle foot system." Gait & posture 32.2 (2010): 191-198.
[12] Vrieling, A. H., et al. "Uphill and downhill walking in unilateral lower limb amputees." Gait & posture 28.2 (2008): 235-242.

- Microprocessor ankle reduces compensatory movements while walking down slopes[13].
- Faster foot flat increases the stability of the prosthetic limb during weight transfer[1].
- Microprocessor ankle allows a more extended and stable knee alignment while loading the prosthetic limb[13].
- Microprocessor ankle reduces the excessive socket pressures on the residual limb[6].
- Microprocessor ankle contributes to patients reporting feeling safer when descending slopes[11].

Slope ascent
- Microprocessor ankle reduces knee hyperextension of residual limb and demand on sound side limb to lift the body up the slope[11].
- Accommodating the slope reduces pressures experienced at the socket[6].
- Allows patient to load more body weight during stance phase on the prosthesis during ascent[11].

7. **Benefits on Stair Ambulation**

Medical Necessity:

A fixed ankle prosthesis limits function on stair ambulation and requires compensatory strategies by persons with lower limb amputation

Benefit from Kinnex™:

Kinnex™ microprocessor controlled ankle provides ankle dorsiflexion and allows users to bring their center of mass more anterior on the step for proper foot placement of their intact side foot. This position allows patients to use their knee and hip musculature in the prosthetic side limb to assist in stepping up and lowering down during stair ambulation.

Supporting Evidence:

- Microprocessor ankle improves knee kinematic and kinetics on stair ascent and descent, more closely mimicking natural human locomotion[14].

- Involved side knee extensors are used more with a microprocessor ankle and patients rely less on their involved side hip extensors[14].

- Microprocessor ankles allow more symmetry in work done by involved and intact limbs[15] because the involved limb tolerates more body weight[15].

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[13] Struchkov, Vasily, and John G. Buckley. "Biomechanics of ramp descent in unilateral trans-tibial amputees: Comparison of a microprocessor controlled foot with conventional ankle–foot mechanisms." Clinical Biomechanics 32 (2016): 164-170.
[14] Alimusaj, Merkur, et al. "Kinematics and kinetics with an adaptive ankle foot system during stair ambulation of transtibial amputees." *Gait & posture* 30.3 (2009): 356-363.
[15] Agrawal, Vibhor et al. "Comparison between microprocessor-controlled ankle/foot and conventional prosthetic feet during stair negotiation in people with unilateral transtibial amputation." *Journal of rehabilitation research and development* 50.7 (2013): 941.