Journal of Conventional Weapons Destruction

Volume 7
Issue 1 *The Journal of Mine Action*

Article 39

April 2003

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Issue 7.1, April 2003
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Victim Assistance Efforts: The Niagara Foot

A team of Canadian researchers and professionals has designed and tested a novel prosthetic foot tailored for active amputees in post-conflict regions.

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The Landmine Issue

It is estimated that over one million people have been killed or maimed by anti-personnel mines since 1975 and that there are approximately 26,000 new victims each year, with 90 percent of the amputees being lower limb amputees.[1] In Thailand alone, there are 530 mine-affected communities, with the majority of these located along the Cambodian border and the remainder along the Burmese border and the Laotian border.[2] Many of the landmine victims live in rural areas without easy access to prosthetic clinics or the sufficient funds to purchase limbs. Compared to countries such as Cambodia, Thailand has a relatively good infrastructure to support its amputee population, and yet is still unable to meet their needs.

Surviving a landmine explosion that results in the loss of a limb can be devastating. Once the physical healing of the patient has occurred, a return to normal activities is desired, especially for one who is dependent on performing manual labour to support oneself, one’s family and one’s community.

Walking and running on uneven terrain. Tending to livestock. Braving the rough, pitted, muddy terrain of a rice field. Lifting and transporting 100-pound bags of rice. Driving a manual tractor. These demanding activities are common for labourers and farmers in the rural regions of Thailand.

In many post-conflict regions, the number of amputees can be so vast that, despite efforts from governmental and non-governmental agencies, prosthetic limbs cannot be fabricated and delivered to meet the needs. Along with the problems of prosthetic component availability, distribution and cost, many of the prostheses shipped to these countries are designed with western clientele in mind. As a result, the prosthetic components used do not adhere to the rugged and active lifestyles of the amputees. Many of these components can survive neither the harsh environmental conditions nor the unforgiving labour-intensive activities performed daily by individuals.

The harsh demands of the terrain and working environment provide a challenge for local prosthetists, governmental agencies and non-governmental agencies supporting victim assistance programs. What is lacking are durable, responsive systems geared towards the needs of the amputees in these regions. A day’s wages are lost every time a patient must travel to the clinic to have a prosthetic limb component repaired or replaced.

A New Invention: Collaboration is the Key to Success

Rob Gabourie, certified prosthetist and orthotist and founder of Niagara Prosthetics & Orthotics Corp. in St. Catharines, Ontario, Canada wanted to tackle this challenge by providing a durable, high-technology solution. Mr. Gabourie has a keen desire to give individuals in post-conflict regions access to high-quality, durable prosthetic components to

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allow them to perform their normal activities. He has developed a series of durable, high-quality prosthetic components designed specifically for active users in the hot, rough climates of many post-conflict regions. The patented Niagara Foot[3] is a novel energy-return prosthetic foot intended to provide improved performance to lower limb amputees. It was developed as part of a programme of The Canadian Centre for Mine Action Technology (CCMAT) by Niagara Prosthetics and Orthotics (St. Catharines, ON) and Queen's University (Kingston, ON) with the collaboration of Dupont Engineering Polymers (Wilmington, DE) and Recto Molded Products (Cincinnati, OH).

A key aspect of the design of the Niagara Foot is the separation of the keel of the foot from the cosmetic cover. A cosmetic cover is generally worn over the keel to provide a more life-like look to the foot. While this concept is not new in high-end, westernised products, its application to victim relief efforts is new. This separation of the foot keel from the cosmetic cover ultimately extends the durability of the foot. Prosthetic feet that have the cosmesis inseparable from the keel encounter a common problem: once the prosthetic foot is damaged, the patient can no longer use it, as the biomechanical capabilities of the foot are compromised. Field studies in Thailand and El Salvador have shown damage to conventional feet to occur within weeks after prosthetic fitting, resulting in patients attempting to walk on broken devices. With the Niagara Foot, any damage to the cosmetic cover does not impair the biomechanical use of the foot. The cosmetic cover can be replaced simply and cheaply by the patient.

The keel of the Niagara Foot is composed of a single, S-shaped part, which acts like a spring in order to provide elastic energy storage and return during the gait cycle. Upon heel strike, the lower C-section or heel deflects upwards, causing the toe portion of the foot to deflect downwards and the contact point to open. As weight is transferred over the foot, energy is released from the heel and the contact point closes. Once contact is made, the compliance of the foot decreases (stiffness increases) in order to prepare for toe-off. During this phase, the toe portion deflects and stores energy. As the toe lifts off, this energy is released to help propel the limb into the swing phase. The energy return principle incorporated into the design of the Niagara foot allows the user to walk more naturally than conventional designs.

The initial design of the Niagara Foot, optimised for a 50–60-kg person, has resulted in a 24-cm-long keel injection moulded using DuPont™ Delrin® acetyl which is capable of dorsiflexing 4–10 degrees with a stiffness on toe-off of 50 kN/m. Although these values are typical for walking on level ground, they are also practical for use in more rugged conditions. Two grades of materials were selected for the same size foot, one geared towards heavier or more active individuals, while the other is tuned for lighter or less active individuals.

The Niagara Foot's simple keel design and use of Dupont™ Delrin® have resulted in an exceptionally durable prosthetic foot that performs well biomechanically for a variety of activities of daily living.

Computational Modeling and Testing is the First Step

In order to predict the behaviour and service life of the Niagara Foot, it was tested in a series of computational, laboratory, clinical and field trials. Using an iterative design approach, the initial design of the prosthetic foot was validated by then Queen's mechanical engineering graduate student, Tara Ziolo, using Finite Element Analysis techniques. As a result of this computational modeling and testing, the design of the prosthetic foot was optimised.

Static and cyclic testing has been performed by researchers at Queen's University, as outlined by International Organisation for Standardisation (ISO) 10328 A60 international standards. Static testing was performed using a compression-testing system, whereby a force is applied to the toe and then the heel of a foot, and held for a period of time. Its purpose is to ensure that the component can meet or surpass standard values that represent high loading conditions, such as jumping. The Niagara Foot strengths exceeded the 3220 N required for heel loading, and 2790 N required for toe loading as outlined in the ISO 10328 A60 standards.

Cyclic testing was undertaken using a fatigue tester designed and built at Queen’s University. It is comprised of four stations, each with a pneumatic loading cylinder for the heel and toe. The cylinders are computer-controlled to produce an axial force waveform at the tibia similar in shape to that observed in normal gait. At the same time, peak force values at the heel and toe are programmed to be consistent with those required in ISO 10328 standard.

For mechanical testing purposes, it is generally assumed that an average adult will walk one million strides per year.[4] Cyclic testing did not produce failures or significant wear when heel and toe peak forces exceeded 120 percent of requirements over 3,000,000 cycles, although a small permanent upward deformation in the heel was observed. The combination of the simple shape and material selection has resulted in a device that is more durable than many conventional designs, which have a much shorter service life.[5, 6]

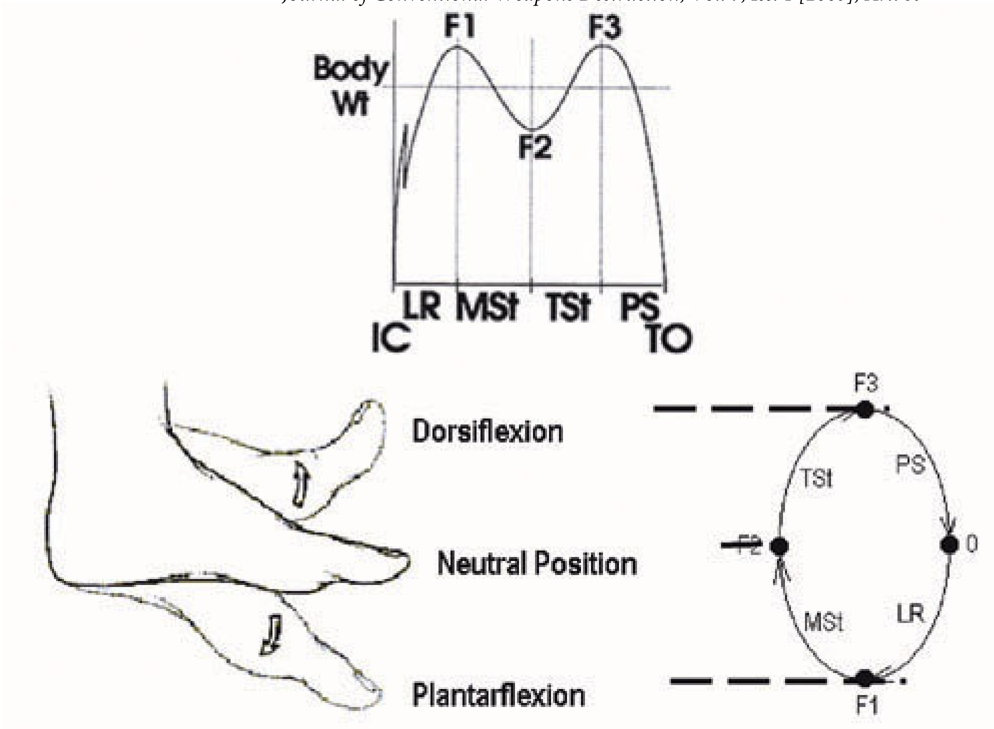
Initial Performance Testing in Canada

Researchers at Queen’s performed a clinical study on one of the first versions of the Niagara Foot (Series 1). Both the Niagara Series 1 Foot and a Solid Ankle Cushion Heel (SACH)-type foot (Solid Attachment/Flexible Endoskeletal, SAFE) were tested with volunteer below-knee amputees. Each subject wore both types of feet for two to five days then was tested in a gait lab using an Optotrak™ optoelectronic motion analysis system integrated with an AMTI™ force plate. With a few minor exceptions, the Niagara Series 1 Foot matched the ground reaction-loading pattern found with a SAFE Foot.

Possibly one of the most important results of the clinical gait trials was the qualitative feedback from the subjects of the trial, which showed that the amputees were satisfied with the Niagara Series 1 Foot in terms of stability, effectiveness and comfort.

Field Trials in Thailand.

With the assistance of the Thailand Mine Action Centre (TMAC), study teams have visited Aranyaprathet Hospital in Thailand on three occasions: initial project kickoff in November 2001; a mid-project visit in May 2002; and a project completion visit in January 2003. During these visits, prosthetic components were observed, patients interviewed and walking performance tests completed.



To further conduct the field trial, a follow-up protocol was developed to support a patient review by local prosthetists after three months—with communication of results by electronic and air mail. Field trials in a rural hospital in Thailand were undertaken with 16 volunteers (age 39.9 +/- 12.3 yrs; height 161.2 +/- 6.5 cm; weight 57.1 +/- 7.2 kg).

All patients were initially wearing SACH Feet and the Niagara Feet were retrofitted onto the existing prosthesis systems. The Niagara Foot increases the loading to other components in the prosthetic system, sometimes causing failure. As such, its use as a retrofit device on older systems should be carefully considered.

The Niagara Foot is an energy-return system. The biomechanical advantages of the device compared to SACH designs were evident since the initial trials and continue to improve with time. Patients are able to detect and appreciate the performance offered by this device, particularly in its ability to return energy during the gait cycle, thereby decreasing the muscular effort required for walking. These conclusions are partially borne out by objective measures of walking performance, indicating a reduced cadence and increased stride length when compared to the original SACH foot in patients. In addition, the gait performance results at six months and one year suggest that patients are becoming more confident with the foot.

The durability of the device is evident. In contrast to the SACH device currently used at the Aranyaprathet Clinic, there were no failures of the keel after six months and one year in all patients, which is consistent with laboratory testing. Devices showed a limited amount of wear in contact regions and no failures present at the one-year mark. This is significant given that the current prosthetic feet used in this clinic in Thailand last for less than three months.

Overall, the patients are happy with the Niagara Foot. They feel it is durable and comfortable to walk in. They often wear the foot while working in the fields or doing manual labour and prefer this foot to their previous foot.

The Next Steps

Feedback from the field trials has been very positive and has resulted in further minor enhancements to the prosthetic foot design, in both the keel and the cosmetic cover. The initial foot design was geared towards users who did not wear shoes. A design allowing the simpler wearing of a shoe is currently being developed. Larger-scaled trials are planned for a number of regions worldwide. In addition, the design of other prosthetic components is currently underway by researchers at Queen's, in collaboration with Rob Gabourie from Niagara Prosthetics and Orthotics.

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