

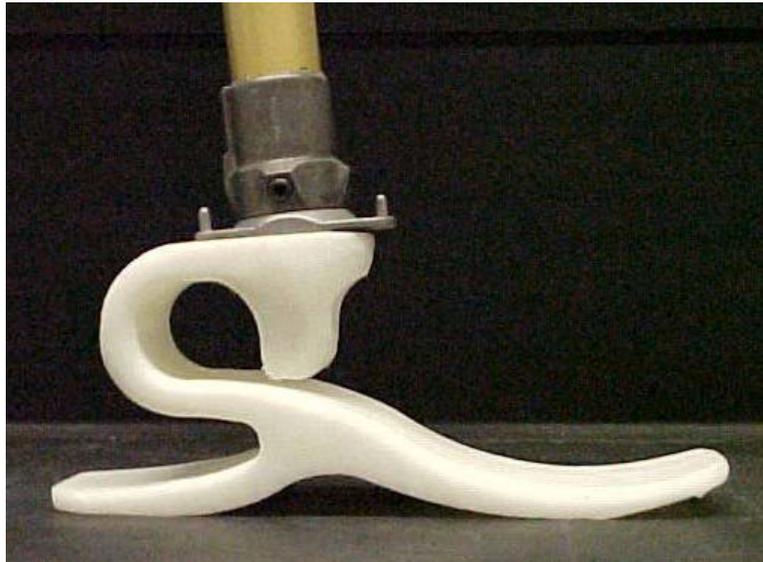


Department of Mechanical Engineering  
Queen's University  
Kingston, Ontario, Canada  
K7L 3N6

---

# Technical Report - Niagara Foot Pilot Study in Thailand

8 - 10 November 2001



*T. Ziolo and J.T. Bryant*

*30 January 2002*

---

## Executive Summary

The Niagara foot is a novel low cost energy-return prosthetic foot intended to provide improved performance in lower limb amputees. It was developed as part of the landmine victims relief 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).

With the assistance of, the Thailand Mine Action Centre (TMAC) a study team visited Aranyaprathet Hospital from November 1, 2001 to November 10, 2001 to perform a clinical trial of the device. The study was conducted on 15 volunteer subjects to get early feedback on the compatibility of the foot with existing prosthetic systems and to determine the initial performance of the device.

All patients were initially wearing SACH (Solid Ankle Cushion Heel) feet and Niagara feet were retrofitted onto the existing prosthesis systems. Although the Niagara foot could be fitted to wooden systems, it should not be used due to the high force demands on the connecting bolt assembly.

From the study it was observed that most patients were able to appreciate the biomechanical differences of the Niagara foot compared to the SACH design. Although there was some initial concern regarding stability, these concerns likely reflected the flexibility of the Niagara foot and the energy return capabilities of it. The mechanism of the energy return system also explains comments regarding the Niagara foot such as "lighter" and softer".

The main challenge with the Niagara foot is cosmesis. Although patients were satisfied with the performance of the Niagara foot, they were generally dissatisfied with the foot's ability to fit inside their current footwear.

## Table of Contents

<i>Executive Summary</i>	2
<i>Table of Contents</i>	3
<i>List of Figures</i>	4
<i>List of Tables</i>	4
<b>INTRODUCTION</b>	5
<i>Background</i>	5
<i>Biomechanics of Niagara Foot Design</i>	6
<i>Mechanical Testing</i>	10
<i>Preliminary Clinical Trial</i>	11
<b>METHODS</b>	12
<i>Patient Demographics</i>	12
<i>Protocol</i>	13
<b>RESULTS</b>	15
<i>Demographics</i>	15
<i>Patient Questionnaires</i>	16
<b>DISCUSSION</b>	20
<b>CONCLUSION</b>	21
<b>REFERENCES</b>	21
<b>ACKNOWLEDGEMENTS</b>	22
<i>Appendix 1 – Patient Testing Protocol</i>	23
<i>Appendix 2 – Questionnaires for Followup in Thailand</i>	30

## List of Figures

<b>Figure 1:</b> Profile of a foot demonstrating motion during the stance phase of gait.	7
<b>Figure 2:</b> Terminology used in describing locations on the Niagara Series 3 foot.	8
<b>Figure 3:</b> Niagara foot (a) side view and (b) front view.	8
<b>Figure 4:</b> Location of applied forces at heel strike and toe off for static analysis.	10
<b>Figure 5:</b> NPO Fatigue Tester.	11
<b>Figure 6:</b> (a) Patient wearing the Niagara foot and (b) one of the activities of daily living demonstrated during initial trials in the clinic.	14
<b>Figure 7:</b> Comparison of original foot and Niagara foot (15 subjects).	18
<b>Figure 8:</b> Comparison of original foot with Niagara foot initially and after 2 days (initial 7 subjects).	19

## List of Tables

<b>Table 1:</b> Demographics of the fifteen patients in the Thailand study.	15
<b>Table 2:</b> Prosthesis systems used initially by study subjects.	15
<b>Table 3:</b> Niagara foot type given to study subjects based on patients weight and activity level.	16
<b>Table 4:</b> Positive comments from the patient questionnaires.	17
<b>Table 5:</b> Additional comments from the patient questionnaires.	17

# INTRODUCTION

## Background

The motivation for this project is to aid in relief efforts by providing victim assistance to those individuals amputated as a result of landmines. Due to the vast number of landmines still in the surrounding countryside of post conflict countries, farmers, nomads, fleeing refugees and children may accidentally detonate a landmine hidden just below the surface of the ground. If the initial blast does not immediately kill the individual and they are able to make it to a hospital, traumatic amputation of the lower extremities is the most common outcome.

Over one million people have been killed or maimed by landmines since 1975 and there are approximately 26 thousand new victims every year with approximately 90% of all amputees being lower limb amputees<sup>1</sup>.

There are at least 50 agencies around the world that provide relief, rehabilitation, education, and aid in demining efforts including landmine relief. The objective of the Niagara Foot Project is to assist in these efforts by providing advanced technology at low cost using state of the art engineering and materials in the design of prosthetic components. Simplicity, durability, functionality and affordability are primary requirements.

The Niagara foot has been developed over the past three years as a result of an intensive project with Queen's University, Niagara Prosthetics & Orthotics, and the Canadian Centre for Mine Action Technology. After initial patient testing by Potter (1999), a cyclic fatigue tester was designed and built at Queen's University. This system conforms to ISO Standards for Lower Limb Prostheses Testing<sup>2</sup> but has a waveform shape and magnitude consistent with that of clinical gait studies<sup>3</sup>. This mechanical testing has indicated acceptable performance of the design.

The purpose of the clinical studies in Aranyaprathet, Thailand between November 1, 2001 and November 10, 2001 was twofold: to determine compatibility and technical feasibility of the design with respect to current prosthetic systems and to determine initial patient acceptance.

---

<sup>1</sup> "Landmine - Statistics", OneWorld International, London, 2001. ([www.oneworld.org/guides/landmines/stats.html](http://www.oneworld.org/guides/landmines/stats.html))

<sup>2</sup> International Organization for Standardization, "Prosthetics - Structural testing of lower-limb prostheses - Reference number ISO 10328-1:1996(E)", International Organization for Standardization (ISO), Geneva, 1996.

<sup>3</sup> Costigan, PA, "Average axial force along the tibia during normal level walking", Unpublished Report, School of Physical and Health Education, Queen's University, Kingston, Ontario, Canada, 2000.

## Biomechanics of Niagara Foot Design<sup>4</sup>

A complete gait cycle is the period between the heel strike of one foot to the next heel strike of the same foot. This cycle is divided into two distinct phases: the stance phase, which is about 60% of the total cycle, and the swing phase, which is the remaining 40%. Both feet are in contact with the ground approximately 25% of the time<sup>5</sup>.

Foot motion consists of two stages, plantarflexion and dorsiflexion (Figure 1). Upon heel strike, the foot undergoes plantarflexion whereby the angle between the sole of the foot and the tibia increase to a value greater than 90 degrees. The end of this phase corresponds to a peak ground reaction force, F1. As the ground contact force moves from the heel to the toe region, the amount of flexion decreases. Upon toe off, the ground reaction force reaches a second peak, F3, and the foot angle reaches maximum dorsiflexion. After this, the angle between the sole of the foot and the tibia begins to decrease and energy is released to propel the body forward.

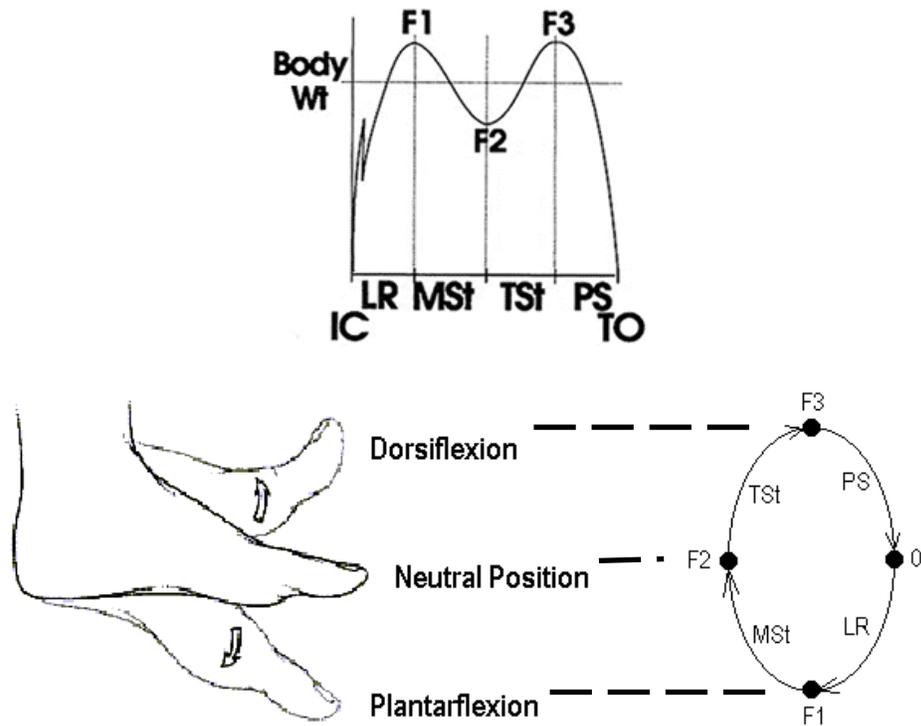
The basic design of the Niagara foot is shown in Figure 2. It is designed to be compatible with any prosthetic system that attaches the foot to the shank using a single bolt. A hole is placed in the upper portion and an opening is provided in the base for tightening tools. In addition, a clearance space is provided at the front to permit the bolt insertion.

The cross section is shown in Figure 3. It is a basic energy return design, similar to many current devices, however it differs in the simplicity of the shape. 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 lift off, this energy is released to help propel the limb into the swing phase.

---

<sup>4</sup> Ziolo, T, "Development and Validation of Performance Criteria for the Niagara Foot", MSc(Eng) Thesis, Department of Mechanical Engineering, Queen's University, Kingston, Ontario, Canada, 2001.

<sup>5</sup> Ayyappa, E, "Normal Human Locomotion, Part 1: Basic Concepts and Terminology", *Journal of Prosthetics and Orthotics*, 9(1), 10-17, 1997.



**Figure 1:** Profile of a foot demonstrating motion during the stance phase of gait<sup>6</sup> Plantarflexion is experienced upon heel strike, neutral position occurs during midstance and dorsiflexion occurs upon toe off. A normal gait cycle is shown in the plot above. The cycle on the right shows how these motions occur during the gait cycle. From the neutral position 0, plantarflexion increases during the loading response (LR) up to the first peak force, F1, after which plantarflexion decreases during the midstance phase (MSt) to the neutral position at F2. From the neutral position at F2, dorsiflexion increases during the terminal stance phase (TSt) up to its peak at F3, and then decreases during the preswing phase to the neutral position at toe off.

<sup>6</sup> "Basic Anatomic Terms", Footmaxx, Toronto, 2001. ([www.footmaxx.com/clinicians/anatomy.html](http://www.footmaxx.com/clinicians/anatomy.html))

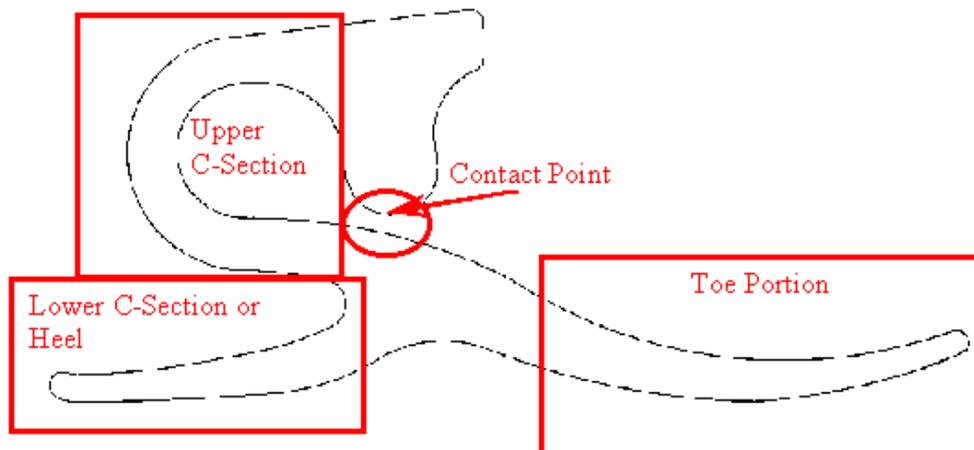


(a)



(b)

**Figure 2:** Niagara foot (a) side view and (b) front view. The foot is designed to be compatible with any prosthetic system that attaches the foot to the shank using a single bolt. A hole is placed in the upper portion and an opening is provided in the base for tightening tools. In addition, a clearance space is provided at the front to permit the bolt insertion.



**Figure 3:** Terminology used in describing locations on the Niagara Series 3 foot.

The peak force applied by a person walking on a level surface is approximately 1.2 times body weight<sup>7</sup>. For a 55 - 60 kg individual, the resulting force applied on the foot is approximately 700 N. During heel strike, the 700 N force was assumed to act at the back of the heel, 15° anterior to the tibial axis. During toe off, the 700 N force was assumed to act midway between the head of the metatarsals and the distal end of the phalanges at an angle of 20° posterior to the tibial axis (Figure 4). Target values for mechanical characteristics in plantarflexion and dorsiflexion were based on McKenzie (1973)<sup>8</sup>. Upon heel strike, a rotation of 10° was chosen and upon toe off, a stiffness of 50 N/mm was chosen.<sup>9</sup>

Design features of the Niagara foot also allow for simple field adjustments to customize the foot for the individual. Removing material from the base of the C-section can increase the deflection angle upon heel strike. By increasing the gap between the contact points of the foot, the stiffness upon toe off can be decreased by delaying the gap closure from mid-stance.

As a result of this analysis, two materials were selected for the same sized foot: Delrin<sup>®</sup> 100ST, a polyacetyl with a modulus of approximately 1.05 GPa<sup>10</sup>, and Delrin<sup>®</sup> 100P, with a modulus of 2.6 GPa<sup>11</sup>. Both materials were fabricated in a single 240 mm length using the same injection mold. The former was intended for subjects in the 45-55 kg weight range and the latter for the range of 55-65 kg.

---

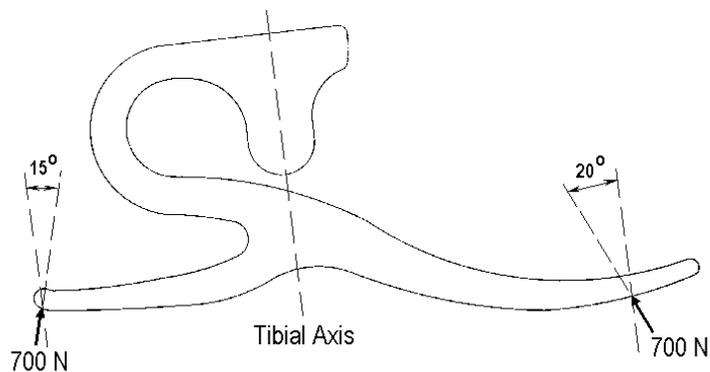
<sup>7</sup> McKenzie, DS and A Muilenburg, "Standards for Lower-Limb Prostheses- Report of a Conference 1977", International Society for Prosthetics and Orthotics, 1978.

<sup>8</sup> McKenzie, DS and A Muilenburg, "Standards for Lower-Limb Prostheses- Report of a Conference 1977", International Society for Prosthetics and Orthotics, 1978.

<sup>9</sup> McKenzie, DS and A Muilenburg, "Standards for Lower-Limb Prostheses- Report of a Conference 1977", International Society for Prosthetics and Orthotics, 1978 and Ziolo, T, "Stress Analysis and Design Optimization of an Injection Molded Prosthetic Foot", Undergraduate Thesis, Mechanical Engineering Department, Queen's University, Kingston, Ontario, Canada, 1999.

<sup>10</sup> Dupont, "Delrin – Product Information Sheet", DuPont, USA, 2001. (<http://www.dupont.com/engpolymers>)

<sup>11</sup> Dupont, "Delrin – Product Information Sheet", DuPont, USA, 2001. (<http://www.dupont.com/engpolymers>)



**Figure 4:** Location of applied forces at heel strike and toe off for static analysis.

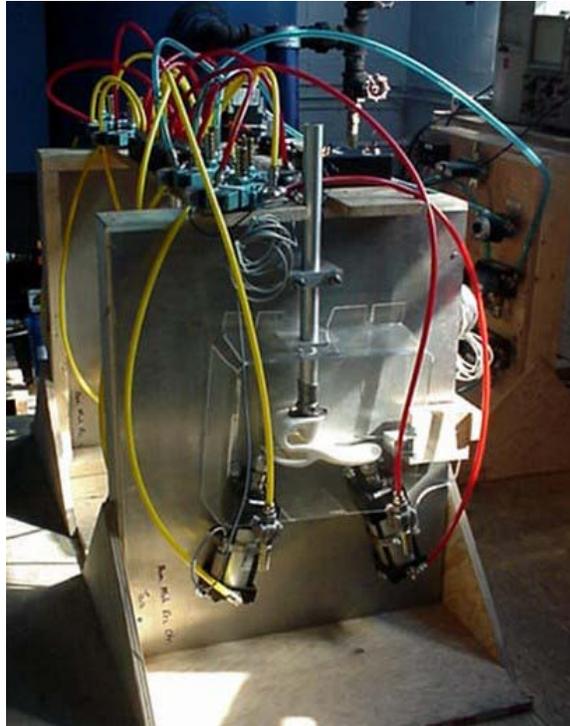
## Mechanical Testing

The International Organization for Standardization (ISO Standard 10328) outlines the test methods using static and cyclic strength tests<sup>12</sup>. The static tests relate to the maximum loads generated, whereas the cyclic tests relate to normal walking activities.

Four samples of the Niagara foot were tested using a modification of the ISO-10328 testing sequence on a custom-built fatigue tester as shown in Figure 5. A dual-peak waveform matching the contact force profile of Figure 1 was imposed using heel and toe actuators with peaks of 970 N at a frequency of 1 Hz. All specimens exceeded a life of greater than 1.7 million cycles before failure.<sup>13</sup>

<sup>12</sup> International Organization for Standardization, "Prosthetics - Structural testing of lower-limb prostheses - Reference number ISO 10328-1:1996(E)", International Organization for Standardization (ISO), Geneva, 1996.

<sup>13</sup> Ziolo, T, "Development and Validation of Performance Criteria for the Niagara Foot", MSc(Eng) Thesis, Department of Mechanical Engineering, Queen's University, Kingston, Ontario, Canada, 2001.



**Figure 5:** NPO Fatigue Tester. The cyclic fatigue tester consists of two test stands each of which house two test stations mounted as mirror images on either side of an aluminum plate. In each station, two computer-controlled pneumatic actuators apply forces to the heel and toe to produce a dual-peak waveform at the tibia.

## Preliminary Clinical Trial

Potter (1999) performed a clinical study on one of the first versions of the Niagara foot (Series 1)<sup>14</sup>. Both the Niagara Series 1 foot and a 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.

This study indicated no statistical difference ( $p > 0.05$ ) in the velocity (Niagara Series 1 – 1.12 m/s, SACH – 1.08 m/min) and cadence (Niagara Series 1 – 100.4 steps/min, SACH – 101.4 steps/min). However, the Niagara Series 1 statistically outperformed ( $p < 0.05$ ) the SACH with respect to stride length (Niagara Series 1 – 1.33 m, SACH 1.27 m) and percent stance phase (Niagara Series 1 – 61.24%, SACH – 64.95%).

---

<sup>14</sup> Potter, DW, "Gait Analysis of a New Low Cost Foot Prosthetic For Use in Developing Countries", MSc Thesis, School of Physical and Health Education, Queen's University, Kingston, Ontario, Canada, 2000.

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, and they indicated no significant difference between the Niagara Series 1 foot and the SAFE foot.

From this study, it was also found that a combination of 4° of plantarflexion and a stiffness of 50 kN/m was acceptable by these patients. It was also found that, with a few minor exceptions, the Niagara Series 1 foot matched the ground reaction loading pattern found with a SAFE foot.

## **METHODS**

### **Patient Demographics**

Thailand was chosen the site for the first clinical trial of the Niagara foot based on an on-going relationship with CCMAT (Canadian Centre for Mine Action Technology), TMAC (Thailand Mine Action Centre) and NPO (Niagara Prosthetics & Orthotics). The logistical arrangements coordinated by CCMAT facilitated the collaboration of Aranyaprathet Hospital, located in the eastern central region of Thailand.

Twenty subjects were recruited by the hospital on the basis of unilateral injury due to landmines and being previous patients at the clinic. Fifteen subjects participated in the study according to the protocol approved by Queen's University Human Ethics Review Board (Appendix 1). Twelve of the fifteen patients were amputated as a direct result of an encounter with a landmine, two were as a result of an encounter with a mortar, and one as a result of infection.

After the interview process, NPO performed a system assessment to determine if the patients' current system was compatible with the new foot and to determine if their current system was in reasonable condition.

## Protocol

The pilot study was three days long with 7 subjects on the first day, the remaining 8 subjects on the second day and a follow-up of the day 1 subjects on the third day.

If the patient's system was compatible and in reasonable condition, the patient's current prosthetic foot was removed and a Niagara foot attached (Figure 6a) without any length adjustments. The patients were asked to walk briefly for an initial alignment of the foot (Figure 6b). The selection of either the Delrin<sup>®</sup> 100ST or the 100P foot was based on the patient's weight and activity level.

All subjects were asked to complete a questionnaire regarding the performance of the foot. The instrument (Appendix 2) was developed by Potter (1999) as part of the initial field study of the Niagara Series 1 foot. There are ten dimensions in the instrument that uses a visual analogue scale for reporting. Three dimensions are based on the general response to the foot itself, two relate to the perception of stability with the device, and two are specific to heel strike and toe off. Two dimensions relate to the muscular effort required to move the limb and a final dimension is intended to determine effects at the limb socket interface. A final question deals with the daily utility of the system.



(a)



(b)

**Figure 6:** (a) Patient wearing the Niagara foot and (b) one of the activities of daily living demonstrated during initial trials in the clinic.

## RESULTS

### Demographics

The fifteen subjects (13M, 2F) accepted into the study were between 29 and 72 years of age (mean age = 39.9 years, standard deviation = 12.3) with 13 males and 2 female subjects. Subjects had a mean height of 161.2 cm (standard deviation=6.5) and weight of 57.1 kg (standard deviation=7.2) (Table 1).

**Table 1:** Demographics of the fifteen patients in the Thailand study.

	Age	Height	Weight
Minimum	29	150	45
Maximum	72	172	69
Mean	39.9	161.2	57.1
Standard Deviation	12.3	6.5	7.2

The prosthesis systems used by the subjects initially included 5 modular and 10 exoskeletal assemblies (Table 2). The latter were constructed with a wooden base for attachment at the foot. Of these, four were severely damaged through the absorption of water and as such unable to hold the nut attachment for the fixing bolt. These were subsequently converted to modular systems by the clinic prosthetists.

**Table 2:** Prosthesis systems used initially by study subjects

Prosthesis System Used	Number of Subjects
Modular	5
Exoskeletal	6
Exoskelatal converted to Modular	4

Interestingly, the average weight for subjects choosing the 100P and 100ST was approximately equal (Table 3). There was a limited range of weights for the subjects and as such the majority of selections were based on activity level, rather than by weight alone.

**Table 3:** Niagara foot type selected for study subjects based on patient weight.

Niagara Foot Type	Number of Subjects	Average Weight [kg]
Delrin® 100P	8	56
Delrin® 100ST	7	58

## Patient Questionnaires

The comparison of the patient responses between the original foot and the Niagara foot are shown in Figure 7. Overall, the Niagara foot was preferred over the original foot across the 10 dimensions of socket comfort, effort in opposite leg, toe off, heel strike, overall effort, walking stability, adaptation, and ease of use. However, in two areas, overall comfort and stability while standing, the original foot was preferred.

The most significant finding was the improved ease of use ( $t=3.9$ ,  $p<0.001$ ). This indicated that subjects preferred their ability to control and use the foot for the walking activities tested in the clinic.

These results were generally consistent two days later on the follow-up visit as shown in Figure 8. Of note is the significant increase in performance through a reduction in effort in the opposite leg ( $t=2.6$ ,  $p<0.05$ ).

The positive general comments from patients are shown in Table 4. These indicated a general trend toward an improved function of the design, especially during walking.

Four patients said they would not be able to walk all day wearing the Niagara foot, however, a majority of patients indicated that it was not possible to wear a prosthetic limb for an entire day under any circumstances. The typical work-rest cycle is: four hours activity, one hour rest with the limb removed and then four

hours of activity. In hot weather, subjects generally work two hours with one hour rest. A significant effect of the foot on their work-rest cycle is not likely.

Additional comments made on the foot are shown in Table 5. The most consistent criticism of the Niagara foot involved the appearance and fit of the foot in their shoes. Specifically, patients commented that the Niagara foot should look more natural and be easier to put into shoes (the heel size was too wide for their shoes).

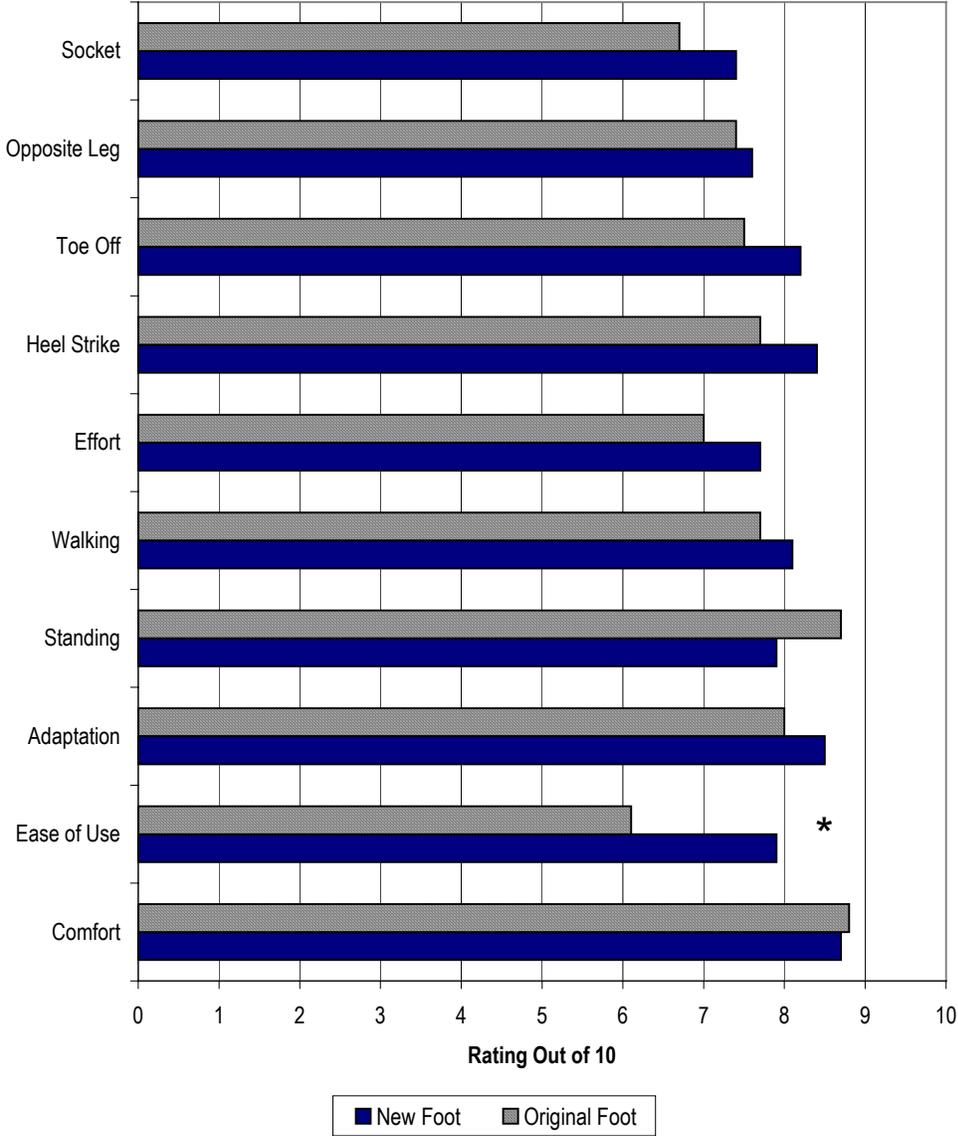
**Table 4:** Positive comments from the patient questionnaires (n=15).

<b>Comment</b>	<b>Number of Patients Who Commented</b>
Niagara foot is softer, lighter, and more comfortable than the old foot on toe off	9
Niagara foot is softer, lighter, and more comfortable than the old foot on heel strike	10
Niagara foot is softer, lighter, and more comfortable than the old foot in general when walking	11
The Niagara foot requires less energy, effort and strength from the opposite leg	6
The Niagara foot requires less energy, effort and strength in general when walking	5
When wearing the Niagara foot, they would be able to walk all day	9

**Table 5:** Additional comments from the patient questionnaires

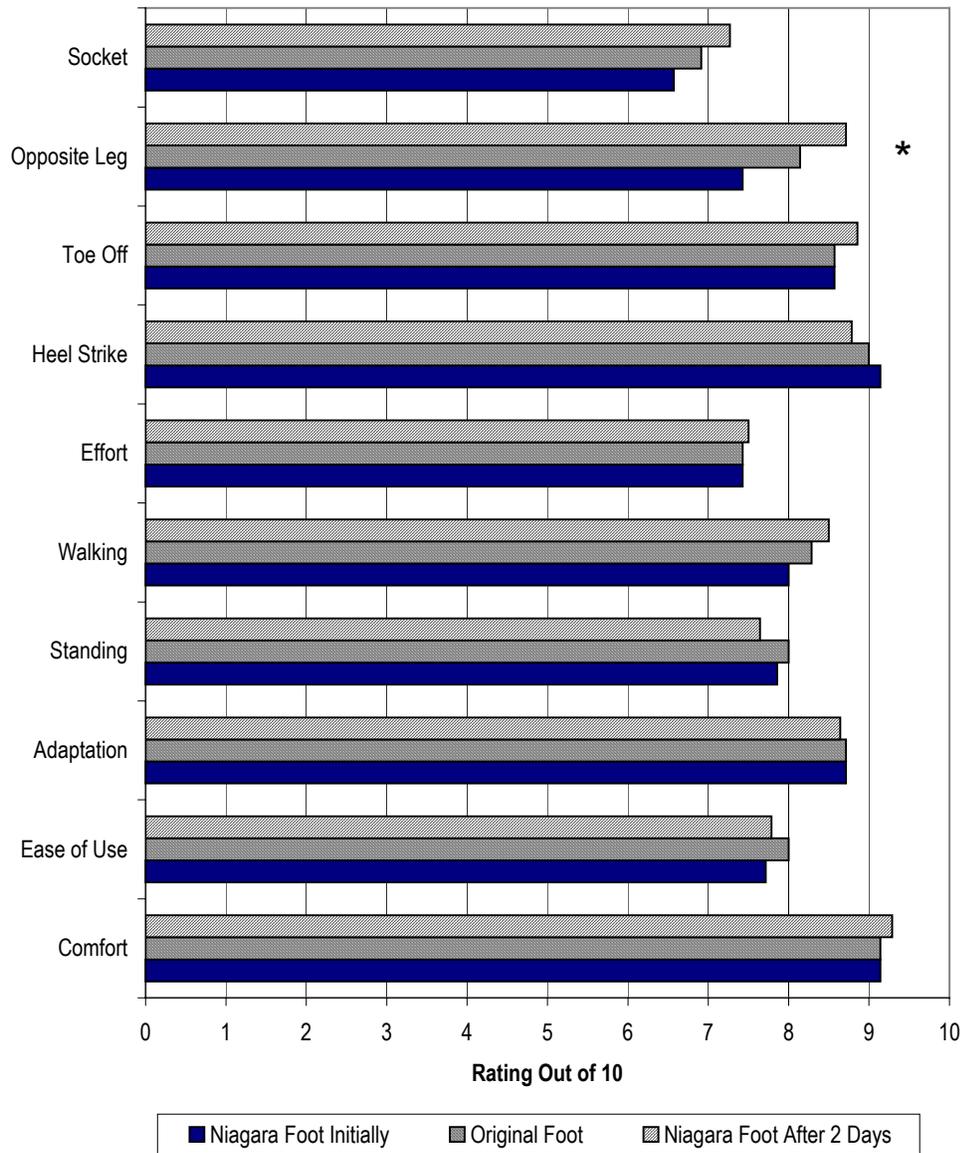
I could comfortably walk and run faster with the new foot whereas I had a hard time walking and running fast with the old one for the old one is harder and there is no spring.
I've tried using it when driving my tractor. The new foot [the Niagara foot] works better than the old one when it comes to driving especially. It takes less energy in driving, for example stepping on the brake.
The only problem is that I couldn't put my shoe on the artificial foot [the Niagara foot]. It's too small. Before I could put shoes on both sides.

**Patient Comparison of Old Foot and Niagara Foot (15 Subjects)**



**Figure 7:** Comparison of original foot and Niagara foot (15 subjects), \* p<0.001

**Comparison of Old Foot With Niagara Foot Initially and After 2 Days  
(Initial 7 Subjects)**



**Figure 8:** Comparison of original foot With Niagara foot initially and after 2 days (initial 7 subjects),  
\* p<0.05

## DISCUSSION

From the study it was observed that most patients were able to appreciate the biomechanical differences of the Niagara foot compared to the SACH design. The initial concern regarding less stability while standing likely reflects the flexibility of the foot. Unlike the SACH foot used by most of the patients, the Niagara foot has some energy return capabilities. Due to the natural motion that occurs throughout the stance phase of gait on a Niagara foot, it appears less stable than a SACH design.

The mechanism of the energy return system also explains comments regarding the Niagara foot such as “lighter” and “softer”. When walking on a SACH foot, the heel compresses to allow for plantar contact. On toe off, the forefoot rolls with a fixed lever arm to permit forward propulsion. This requires action on the affected side and the contralateral hip to lift the foot and allow toe clearance.

In the Niagara foot, energy is required to compress the heel. However, this energy is stored and released during midstance thus accelerating the foot forward. As the forefoot deflects, the energy stored is again released as the foot propels forward. As such, less effort is needed at the hip on either the affected or contralateral side to produce toe clearance. This is consistent with overall findings of ease of use and decrease in effort on the opposite side.

The Niagara foot is compatible with most systems currently on the market. In the case of wood assemblies, the connection between the foot and the pylon posed some problems since it must be strong enough to transmit the moment exerted by the foot on the pylon. This moment is transmitted through a force couple between the contact force and the connecting bolt. In the Niagara foot, the distance between the contact point and the bolt is smaller, requiring higher forces to transmit the same moment. As such, a stronger bolt connection is required with the new device.

The main challenge in the design is cosmesis. Although patients were satisfied with the performance of the Niagara foot, they were generally dissatisfied with the foot’s ability to fit inside their current footwear. The cover was originally designed to be used barefoot or in sandals, however, the majority of clients use athletic footwear during their activities of daily living.

## CONCLUSION

The biomechanical advantages of the Niagara foot compared to the SACH foot are evident in these initial results. Patients are able to detect and appreciate the improved performance offered by this design, particularly in its ability to return energy during the gait cycle thereby decreasing the muscular effort for walking.

The Niagara foot is compatible with most international prosthetic systems. However, it should not be used with systems with wooden components at this time because of the high force demands it places on the bolt assembly. Any decrease in strength of this connection is potentially a point of failure.

There is a need to modify the shape of the foot to permit fitting into sports footwear and to provide a broader range of sizes for this purpose. Of note, however, is that the biomechanical performance of the one size of foot could accommodate a broad range of clients due to the availability of materials with different mechanical properties.

## REFERENCES

"Basic Anatomic Terms", Footmaxx, Toronto, 2001.  
([www.footmaxx.com/clinicians/anatomy.html](http://www.footmaxx.com/clinicians/anatomy.html))

"Landmine - Statistics", OneWorld International, London, 2001.  
([www.oneworld.org/guides/landmines/stats.html](http://www.oneworld.org/guides/landmines/stats.html))

Ayyappa, E, "Normal Human Locomotion, Part 1: Basic Concepts and Terminology", *Journal of Prosthetics and Orthotics*, 9(1), 10-17, 1997.

Costigan, PA, "Average axial force along the tibia during normal level walking", Unpublished Report, School of Physical and Health Education, Queen's University, Kingston, Ontario, Canada, 2000.

Dupont, "Delrin – Product Information Sheet", DuPont, USA, 2001.  
(<http://www.dupont.com/engpolymers>)

International Organization for Standardization, "Prosthetics - Structural testing of lower-limb prostheses - Reference number ISO 10328-1:1996(E)", International Organization for Standardization (ISO), Geneva, 1996.

McKenzie, DS and A Muilenburg, "Standards for Lower-Limb Prostheses- Report of a Conference 1977", International Society for Prosthetics and Orthotics, 1978.

Potter, DW, "Gait Analysis of a New Low Cost Foot Prosthetic For Use in Developing Countries", MSc Thesis, School of Physical and Health Education, Queen's University, Kingston, Ontario, Canada, 2000.

Ziolo, T, "Stress Analysis and Design Optimization of an Injection Molded Prosthetic Foot", Undergraduate Thesis, Mechanical Engineering Department, Queen's University, Kingston, Ontario, Canada, 1999.

Ziolo, T, "Development and Validation of Performance Criteria for the Niagara Foot", MSc(Eng) Thesis, Department of Mechanical Engineering, Queen's University, Kingston, Ontario, Canada, 2001.

## **ACKNOWLEDGEMENTS**

### **Niagara Prosthetics & Orthotics Corporation**

547 Glenridge Avenue, St-Catherines, Ontario, Canada, L2T 4C2

Rob Gabourie  
Phone: 905-688-2553

### **Canadian Centre for Mine Action Technology (CCMAT)**

National Defence Headquarter, Constitution Building, 305 Rideau Street, 8<sup>th</sup> Floor, Ottawa, Ontario, Canada, K1A 0K2

Major Harry Burke  
Phone: 613-996-5193

### **Thailand Mine Action Centre (TMAC)**

183 Songprapa Rd, Sigun, Donmuang, Bangkok, Thailand, 10210

Major General Thamasak Senivongse  
Phone: 662-905-1820

Major General Gitti Suksomstarn  
Phone: 662-905-1685

### **Canadian Embassy**

15<sup>th</sup> Floor, Abdulrahim Place, 990 Rama IV Road, Bangkok, Thailand, 10500

James Trottier  
Phone: 662-636-0560 x3250

### **Aranyaprathet Hospital**

Aranyaprathet District, Sakaew Province, Thailand, 27120

## Appendix 1 – Patient Testing Protocol

### *Purpose and Rationale of Proposed Research*

#### **Background**

The current project's motivation is the ongoing problem of amputations resulting from land mines, especially in developing and post-conflict countries. About 70 people per day are killed or injured due to landmines, of which 110 million still lay active in the ground on every continent ([www.oneworld.org/guides/landmines/stats.html](http://www.oneworld.org/guides/landmines/stats.html)). The majority of amputees are affected in the lower limb, below the knee (BK). The most common approach to provide prostheses for these patients is to use a modular system composed of a foot, pylon and socket. Feet are generally available in a series of sizes and styles, while sockets require custom fitting to ensure proper load transfer to the residual limb. All components are expensive by world standards, since the majority of amputees are in developing countries. It is proposed that a modular low-cost BK prosthesis system can be produced with modern design and fabrication methods.

In 1998, the Government of Canada formed the Canadian Centre for Mine Action Technologies (CCMAT) as part of its Mine Action Initiative. The purpose of CCMAT is to develop new technologies for humanitarian demining. As one of its projects, the Centre teamed with the National Research Council of Canada under the IRAP program to fund the development of the first component in the modular system, the Niagara Foot. This was achieved through the collaboration of a Canadian Company (Niagara Prosthetics and Orthotics) and Queen's University. The modular foot component shown in Figure 1 is unique because of its single unit construction and its ability to be mass-produced in a few standard sizes at a cost of approximately one-quarter that of currently available feet. A second phase of the study has been funded through Materials and Manufacturing Ontario (MMO) for the development of a modular socket component.

The foot has undergone a number of design revisions and mechanical testing to ensure that it meets current performance standards for strength and durability. The aim of this project is to perform a pilot study for clinical trials using the device. At the same time, measurements of the residual limb of volunteer subjects will be obtained for the future development of prosthetic socket components.



**Figure 1.** Niagara Foot prosthetic component. The one-piece component facilitates plantarflexion on heel strike and significant energy return on toe-off. The component is compatible with existing prosthetic systems such as the Otto Bock units shown.

## **Objectives**

The specific objectives of this study are:

1. To determine whether the Niagara Foot design can be fit to BK amputees in a setting typical of the intended client population of landmine victims in a post-conflict region.
2. To determine the satisfaction of 20 clients fitted with the component using a standard instrument.
3. To obtain anthropometric data regarding the size and shape of residual limbs for a range of typical clients in population intended for the design of modular sockets.

## **Procedures**

The Government of Canada, through CCMAT, has established a collaborative project with the Thailand Mine Action Centre (TMAC) in Aranya Thailand. The Thailand group has arranged that trained prosthetic and orthotic professionals will meet with members of the Niagara Foot design team to fit 20 BK amputees at the Centre's prosthetic clinic. Fitting the component follows the same clinically accepted procedures for aligning and assessing the prosthetic limb as used in any other modular component. This may include obtaining a plaster cast of the residual limb for fabricating the socket in primary (first-time) or revision fittings.

As part of the study, patients will be asked to complete a subject questionnaire. If a cast is used, patients will be asked to allow the research team to use measurements made from the cast in the future design of modular socket components.

## **Analysis of Results**

The results of the questionnaire will be compared to those of a previous study of five subjects (Potter, D., M.Sc. Thesis, School of Physical and Health Education, 1999) to indicate any gross differences in the outcomes among the two cohorts. The variances observed in subject responses will be used to perform a power analysis for the planning of a future larger clinical trial aimed at determining the efficacy of the Niagara Foot.

Plaster casts will be returned to Canada and analysed by digitizing the inner surface of each sample and creating a computer aided drawing file of the shape. Specific dimensions will be analysed to estimate variances and provide sample size estimates for more accurate statistically model the shape of residual limbs in Thai BK amputees.

## ***Methodology and Procedures***

1. Patients will be recruited and interviewed according to the procedures indicated in the Recruitment Protocol.
2. The patient will be examined by prosthetists on staff at Aranya District Hospital and by Mr. R. Gabourie, developer of the Niagara Foot. Mr. Gabourie is part of the clinical team delivering the device on behalf of the Canadian Centre for Mine Action Technology.
3. The existing prosthesis will be removed and refit with the Niagara Foot using standard procedures for alignment and fitting.

- a. In some cases, the residual limb will be cast. This is a standard procedure in which plaster casting tape is placed around the limb and removed when hardened.
4. Patients will be asked to perform a variety of simple activities including walking at slow and fast paces, ascending and descending stairs, and directional changes.
5. After this brief accommodation procedure, patients will fill out the questionnaire form (Appendix 2).
6. Patients will be asked if they wish to keep the new foot or replace it with their original device.
  - a. If a patient elects to return to the original device, it will be refit according to standard practice.
  - b. If a patient elects to keep the new foot she/he will be informed that they will be approached to participate in a followup study at a later date, and that this information will be placed in their medical record. They will be informed at this time that any participation in the follow-up study will be voluntary.

#### ***Recruitment Protocol***

1. Potential patients will be identified by clinical staff at Aranya District Hospital.
2. The patient will be approached by Dr. Bryant and the interpreter and introduced by the clinical staff.
3. In a separate room, the patient will be introduced to the project and lead through the Letter of Information, point by point.
4. The patient will be asked if their are any constraints on their time that may affect their participation in the study.
5. The patient will be encouraged to ask questions through the interpreter.
6. The patient will then review a version of the Permission Form translated into Thai.
7. If the patient agrees and signs the form, then the procedures in Methodology and Procedures will be followed.

### ***Letter of Information***

1. This study is being conducted by Dr. J.T. Bryant, Queen's University, Kingston, Canada, in association with members of the Thailand Mine Action Centre and the Canadian Centre for Mine Action Technology.
2. The aim of this project is to evaluate a design for a new prosthetic foot and to assist in the design of a new socket for artificial legs. The reason that we wish to develop new components is to be able to make them less expensive to produce while at the same time being safe, effective and durable. This may make it possible for more people to have a prosthetic leg, since the parts will be more affordable.
3. Procedures:
  - a. If you agree, you will be fitted with a new foot and asked to fill out a questionnaire describing your opinion of how well it functions. Your prosthetist may have to remove your current foot and adjust the parts to make the new foot work properly when you walk. You will then be asked some questions about how well you think the foot works. This information will be used by the designers to make changes to the foot if they are needed. After the questioning session, you may elect to keep the new foot or have your old one replaced as it was originally.
  - b. You may be asked if a plaster cast can be taken of your residual limb. If you agree, it will require you to have your socket removed and plaster-filled bandages wrapped around your limb until the material hardens. This cast will be removed after a few minutes and your socket replaced as it was originally. The cast will be used for measuring how well your socket fits your limb. The cast will be then sent to Canada and measured using a computer. This information will be combined with information from other casts to help designers make a new, less expensive socket.
  - c. The process will take approximately two hours and not more than two and one-half hours. Part of this time will be used to discuss our procedures to make sure you understand what we are asking you to do and to explain why we want to do this study. You will also be given some time to think about whether you want to participate.
  - d. During the period when it is necessary to adjust the foot, it may require a number of tries before it is correct and may be frustrating.
  - e. If you elect to keep the new foot, you may be asked if you wish to be contacted later to ask if you would return to the clinic.
4. There are no known physical, psychological, economic or social risks associated with the study.
  - a. Any prosthetic foot component may break. When testing the new foot on a machine, it lasts the equivalent of at least eighteen months use. However, this time may be greater or less depending on how you use the foot. When the foot fails, it becomes useless because either it is too soft or it breaks into two pieces. If it breaks, it may do so suddenly, and

you may fall. However, this same thing can happen when wearing any prosthetic foot.

- b. If you elect to keep the new foot, the investigators will retain your original components if you wish. If the new foot fails, you may return to the clinic and either have it replaced or have your original components restored.
5. Participation in this study is voluntary and you are free to withdraw at any time. If you do not wish to participate in the study or you wish to withdraw, this will not prejudice in any way your future care as a patient of the clinic. If you wish to withdraw during the study, you should inform the translator or a clinic staff member, who will communicate this to the investigators immediately.
6. You need not answer any questions that you find objectionable or which make you feel uncomfortable.
7. All information collected will be recorded in writing on printed forms and later placed in a computer.
  - a. Photographs will be taken during the fitting of the foot and, if performed, casting of the residual limb. Whenever possible, these photographs will not permit the identification of the individual. These records are standard scientific practice to allow researchers to review the study when they are analysing the results for a number of patients. You may elect to not have photographs taken and this will not affect the success of the study. Alternatively, you may wish to review the photographs and select those that the investigators may keep.
8. Your name will be recorded only on the permission form in association with this study. The forms will be retained by Dr. Bryant and will not be shared with any agency, group, or government.
  - a. If you elect to keep the foot, it will be necessary to identify this fact in your patient records.
9. The data collected in this study will be retained at Queen's University, Kingston, Canada.
  - a. Individual patients will be assigned a reference number. This number will be recorded on the permission form and held in a secure area in the University.
  - b. No publication will permit the identification of an individual involved in the study. Only grouped data will be presented so that no one person could be uniquely identified from physical descriptions or descriptions of activities of daily living.
  - c. Any photographs published will be altered in such a way that the individual cannot be identified.
  - d. All data collected in the study will be retained for a period of three years, after which it will be destroyed by confidential shredding and the deletion of electronic records.

10. Publication of the results will be made either at scientific conferences or in academic journals. These will be used primarily by scientists to help develop new prosthetic components.
  - a. A summary report will be provided to the Thailand Mine Action Centre and to the Canadian Centre for Mine Action Technology. This report may be widely distributed in the governments of Thailand and Canada and will be used to evaluate the success of the project to design new prosthetic components.
  - b. A report will be provided to the companies associated with the design and manufacturing of the foot. These include, but are not limited to: *Niagara Prosthetics and Orthotics Inc.*, St. Catharines, Canada and *Dupont Ltd.*, Wilmington, USA. These companies may use some of this information for commercial purposes such as marketing and public relations.
  - c. Data from measurements made from plaster casts will be used in the design of a new prosthetic socket system. These data may be made available to scientific groups other than the investigators for similar purposes.
11. There is no remuneration for participation in the study. However, any expenses associated either with the fitting the new foot or refitting the original foot will be paid for by the investigators and will result in no cost to the patient. These expenses will be paid whether or not the patient completes the study.
12. If you have any concerns, questions or complaints regarding this study you are to contact Dr. J.T. Bryant, c/o The Canadian Embassy, Bangkok. In your communications, refer to the title: *Pilot study of the Niagara Foot, November 2001*.

**Permission Form**  
**Pilot study of the Niagara Foot in Aranya, Thailand.**

Participant Name \_\_\_\_\_  
Reference Number \_\_\_\_\_

1. I understand that I will be participating the a research study titled: *Pilot study of the Niagara Foot in Aranya, Thailand.*
2. I have reviewed the Letter of Information. I have had the opportunity to ask questions about the study and they have been answered to my satisfaction.
3. I understand that the purpose of this study is to evaluate a design for a new prosthetic foot and to assist in the design of a new socket for artificial legs.
4. My involvement consists of:
  - a. Having a new prosthetic foot installed and adjusted on my prosthetic limb
  - b. Answering a number of questions on a questionnaire form
  - c. Having photographs taken of the component and its adjustment
  - d. Having a cast taken of my residual limb
5. I understand that I may elect to keep my new prosthetic foot. If I do so, this information will be entered into my patient record.
6. I understand that I can contact Dr. J.T. Bryant through the Canadian Embassy in Bangkok if I have any concerns, questions or complaints about the study.
7. My participation in this study is voluntary and I understand that I may withdraw at any time by informing the interpreter or the clinic staff.
8. I understand that confidentiality regarding my participation will be assured.
  - a. The reference number recorded on this permission form will be held in confidence in a secure area in Queen's University, Kingston, Canada.
  - b. No publication will permit my identification in the study. Only grouped data will be presented so that I cannot be uniquely identified from physical descriptions or descriptions of activities of daily living.
  - c. Any photographs published will be altered in such a way that I cannot be identified.
  - d. All data collected in the study will be retained for a period of three years, after which it will be destroyed by confidential shredding and the deletion of electronic records.

Signature \_\_\_\_\_  
Date \_\_\_\_\_

## Appendix 2 – Questionnaires for Followup in Thailand

Patient feedback questionnaire from Potter (1999)

Date \_\_\_\_\_

### Subject Questionnaire

Name \_\_\_\_\_

Subject Code \_\_\_\_\_

Height \_\_\_\_\_

Weight \_\_\_\_\_

Leg Amputated      Left     Right

Cause of Amputation \_\_\_\_\_

Type of Prosthetic(s) currently used [please list in order of most used – least]

1 \_\_\_\_\_

2 \_\_\_\_\_

3 \_\_\_\_\_

4 \_\_\_\_\_

#### Activity Level

Sedentary

Somewhat active

Active

Very Active

Athletic

Elite Athlete

Evaluation of Prosthetic

SACH

NPO

Comfort of the prosthetic	Excellent	Average					Poor			
	10	9	8	7	6	5	4	3	2	1
Ease of Use	Excellent	Average					Poor			
	10	9	8	7	6	5	4	3	2	1
Ease of Adaptation	Excellent	Average					Poor			
	10	9	8	7	6	5	4	3	2	1
Stability when Standing	Excellent	Average					Poor			
	10	9	8	7	6	5	4	3	2	1
Stability when Walking	Excellent	Average					Poor			
	10	9	8	7	6	5	4	3	2	1
Minimizes muscular effort	Excellent	Average					Poor			
	10	9	8	7	6	5	4	3	2	1
Heel Strike Feels Good	Excellent	Average					Poor			
	10	9	8	7	6	5	4	3	2	1
Toe Off Feels Good	Excellent	Average					Poor			
	10	9	8	7	6	5	4	3	2	1
Opposite Leg Feels Good	Excellent	Average					Poor			
Good	10	9	8	7	6	5	4	3	2	1
Limb/Socket Contact is Good	Excellent	Average					Poor			
	10	9	8	7	6	5	4	3	2	1

Do you feel you could use this foot to walk on for an entire day Y  N

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

New patient feedback questionnaire developed from Potter (1999) work

<b>Feedback for Niagara Foot</b>	
<b>Subject ID:</b>	 Excellent  Average  Poor
	10 9 8 7 6 5 4 3 2 1
1. Comfort of the prosthetic	
2. Ease of use	
3. Ease of adaptation	
4. Stability when standing	
5. Stability when walking	
6. Minimizes muscular effort	
7. Heel strike feels good	
8. Toe off feels good	
9. Opposite leg feels good	
10. Limb/Socket contact is good	
11. Do you feel that you could use this foot to walk on for the entire day? Yes <input type="checkbox"/> No <input type="checkbox"/>	
<b>Comments:</b>	
<b>Thank-you!</b>	

