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Midterm Report

Niagara Foot Pilot Study in Thailand

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EXECUTIVE SUMMARY

The Niagara foot 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. Catherines, 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 on 15 volunteer subjects. A follow-up protocol was developed to permit a patient review at 3 months by local prosthetists with communication of results by electronic and air mail. At 6 months, a study team from Canada visited the clinic to interview patients and to observe the foot components directly. The one-year study will be completed in a final visit to Aranyaprathet in December 2002. The results of the initial study are detailed in a separate document: *Technical Report – Niagara Foot Pilot Study in Thailand*. (January 2002). This report documents the results of the 3-month and 6-month follow-up studies.

The Niagara Foot is a low-cost energy-return system. The biomechanical advantages of the device compared to SACH designs were evident in 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 compared to the original SACH foot in patients.

The flexibility of the heel is a concern for some patients. Increased flexibility under load and during standing suggests to some a lack of stability for activities on uneven terrain. However, the gait performance results at six months suggest that patients are becoming more confident with the foot. The Niagara Foot also 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 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 in all patients, which is consistent with laboratory testing. Devices showed a limited amount of wear in contact regions and a small permanent upward deformation in the heel region. However, there were a number of failures in the cosmetic foot cover. In the next phase of the project, this will be redesigned to reduce the tendency to rip, retain water, and make it difficult to fit into athletic and dress footwear.

INTRODUCTION

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. Catherines, 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. The results are detailed in a separate document: *Technical Report – Niagara Foot Pilot Study in Thailand* (January 2002).

All patients were initially wearing SACH (Solid Ankle Cushion Heel) feet and so the Niagara feet were retrofitted onto the existing prosthesis systems. The study team observed that many wooden systems were saturated with water and structurally degraded. Although the Niagara Foot can be fitted to wooden systems this should be avoided because the force demands imposed by the Niagara Foot on the connecting bolt assembly could exceed the structural capacity of the wooden systems causing them to break.

From the initial study it was observed that most patients were able to appreciate the biomechanical differences of the Niagara foot compared to the SACH design. At the beginning of the study the patients expressed some initial concerns regarding standing stability of the Niagara Foot that likely reflected the inherent flexibility of the design compared to the less compliant SACH device. However, patients give the Niagara Foot a higher score for standing stability than the SACH foot. The patients continue to report that the Niagara Foot feels lighter and softer than the SACH design which is attributed to the energy return mechanism built into the Niagara Foot.

The main challenge with the Niagara foot is its 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 issue of fit will be resolved during the production engineering phase of the project where the requirements for designing Niagara Feet for both physical size and weight will be addressed.

To further conduct the clinical trial, a followup protocol was developed to permit a patient review at 3 months by local prosthetists with communication of results by electronic and air mail. At 6 months, a study team from Canada visited the clinic to interview patients and to observe the foot components directly. The one-year study will be completed in a final visit to Aranyaprathet in December 2002. This report documents the results of the 3-month and 6-month followup studies.

FOLLOWUP PROTOCOL

A detailed description of the followup protocol is provided in Appendix 1. All logistics for the study were arranged by CCMAT in cooperation with TMAC and the Aranyaprathet Hospital. The protocol consists of two parts, a patient questionnaire and a prosthetist questionnaire.

There are ten dimensions in the patient questionnaire 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. These are grouped into categories of *Comfort, Dynamic Performance, and Muscular Performance.* The scoring on these scales is relative and relies on the initial score of the subject for control. As such, the values obtained are valid for documentating changes over time and direct comparisons of designs within the same subject. However, this approach does not produce values that can be compared to other studies.

The prosthetist questionnaire focuses on an inspection of the foot itself. A detailed examination of the component is performed to determine any sites of failure, cracking, wear, or cover failure. In addition, a photograph is obtained of the lateral profile positioned on a template of the original shape to determine any permanent deformation in the component.

3-MONTH FOLLOWUP

Patients were seen at the Arayaprathet Hospital during the February 2002 visit. Two of the original patients had not returned to the study: one is now deceased and the other had left the country. Because of these circumstances the prosthetists at the Aranyaprathet Hospital found two new patients and in addition to those new patients one of the prosthetists, an above knee amputee, agreed to participate. There are now 16 patients taking part in the study.

Patients filled out a questionnaire postcard and returned them to Queen's University by airmail. The prosthetists examined the feet and returned their responses by email. In the case of failed components, photographs were taken and forwarded to the study group.

6-MONTH FOLLOWUP

A study team consisting of Dr. T. Bryant and Major H. Burke visited the Aranyaprathet Hospital May 14-16, 2002. Half the patients were seen each day. All patients were interviewed through a translator and the patient questionnaire form completed. The study team performed the inspection of the prosthetic systems and completed the prosthetist questionnaire.

Additional physical tests were performed to measure the walking performance of patients with the Niagara Foot and their original SACH foot. Using the protocol described in Appendix 2, a 15-m walking test was performed to determine gait speed, cadence and stride length under the two conditions. These results were compared to those of an earlier study on a cohort of 5 North American patients (Potter, 2000). This study indicated how subjects adapted to the foot by changing their walking patterns. It is generally accepted for a given walking speed that fewer, longer strides are more efficient than many shorter strides, and that an option exists for each patient.

On the final day, three patients allowed Dr. Bryant to examine what they did on a daily basis to observe the types of activities being undertaken using the Niagara Foot. Patients were observed engaged in their typical work day. Photographs and patient comments were obtained in these sessions.

QUESTIONNAIRE RESULTS

The mean scores for the three-month and six-month follow-ups are shown in Tables 1-3 and Figures 1-3. Also indicated are the mean scores attained for the old foot and the initial fitting of the Niagara Foot. They have been grouped in three areas: comfort, dynamic performance, and muscular performance.

Comfort. An increased score for ease of adaptation has been observed over the six-month period that is consistent with other patient comments. Overall, comfort of the prosthetic system has not changed compared to the original foot. This is expected since comfort is often dominated by the socket component. Of interest is the unexpectedly high score for limb-socket contact in the six-month responses since it is not typical for a particular foot design to greatly affect the comfort at this interface. This may be a statistical anomaly and conclusions will be reserved until the one-year review: it may be that an energy return foot design reduces some impact loading due to its controlled flexibility at heel strike and toe-off.

Dynamic Performance. The dynamic performance scores increased uniformly over time for stability when walking and toe-off. This suggests a continuation of the adaptation period for patients and further indicates improved performance of the foot during locomotion. Heel strike and standing stability have not changed markedly compared to the original foot, due mainly to the flexibility of the heel as indicated in the patient comments.

Muscular Performance. The most dramatic improvements in scores compared to the original foot occurred in ease of use, minimization of muscular effort and improvement to the opposite leg. This strongly supports the biomechanical principles of design of the device as an energy return system. These scores are also reflected in patient comments at 3 and 6 months.

The interaction of these variables reflects how the foot responds during heel strike and toe-off. In a SACH foot, the heel "collapses" after it strikes, and provides little stiffness at toe off. As a result, the patient must lift the leg using musculature at the hip and by rotating on the opposite leg. In contrast, an energy return foot stores energy at heel strike that assists in moving the foot to mid-stance. At toe-off, the propulsive force is also stored elastically and assists in accelerating the foot into the swing phase. As a result, less muscular effort is required at the hip and by the opposite limb.

Table 1: Questionnaire results for comfort. Numbers are based on questionnaire filled out by patients using the Niagara Foot. Each question is based on a scale from 1 – 10.

	Comfort of the Prosthetic	Ease of Adaptation	Limb/Socket Contact is Good
Old Foot	8.9	8.0	6.9
New Foot (Initially)	8.6	8.6	7.6
New Foot (3 Month Follow-Up)	8.7	9.0	6.2
New Foot (6 Month Follow-Up)	8.8	8.9	9.1

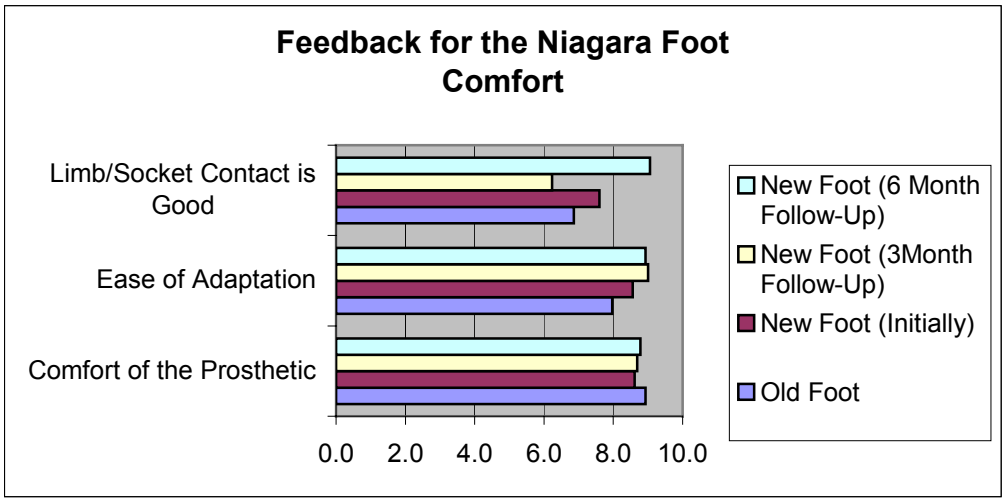

Figure 1: Average results from questionnaires given to the patients using the Niagara Foot, regarding comfort.

Table 2: Questionnaire results for dynamic performance. Numbers are based on questionnaires filled out by patients using the Niagara Foot. Each question is based on a scale from 1 – 10.

	Stability When Standing	Stability When Walking	Heel Strike Feels Good	Toe Off Feels Good
Old Foot	8.7	7.7	7.8	7.5
New Foot (Initially)	8.1	8.1	8.5	8.2
New Foot (3 Month Follow-Up)	8.4	8.3	7.1	8.5
New Foot (6 Month Follow-Up)	9.0	8.8	8.5	8.7

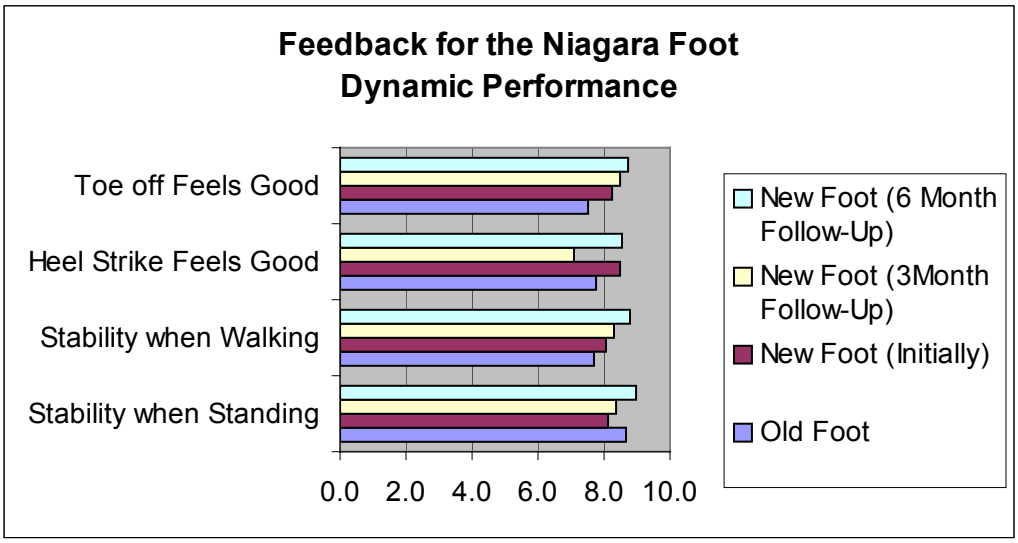

Figure 2: Average results from questionnaires given to the patients using the Niagara Foot, regarding dynamic performance.

Table 3: Questionnaire results for muscular performance. Numbers are based on questionnaires filled out by patients using the Niagara Foot. Each question is based on a scale from 1 – 10.

	Ease of Use	Minimizes Muscular Effort	Opposite Leg Feels Good
Old Foot	6.4	7.1	7.4
New Foot (Initially)	8.0	7.9	7.6
New Foot (3 Month Follow-Up)	8.9	7.8	9.0
New Foot (6 Month Follow-Up)	8.8	8.9	8.6

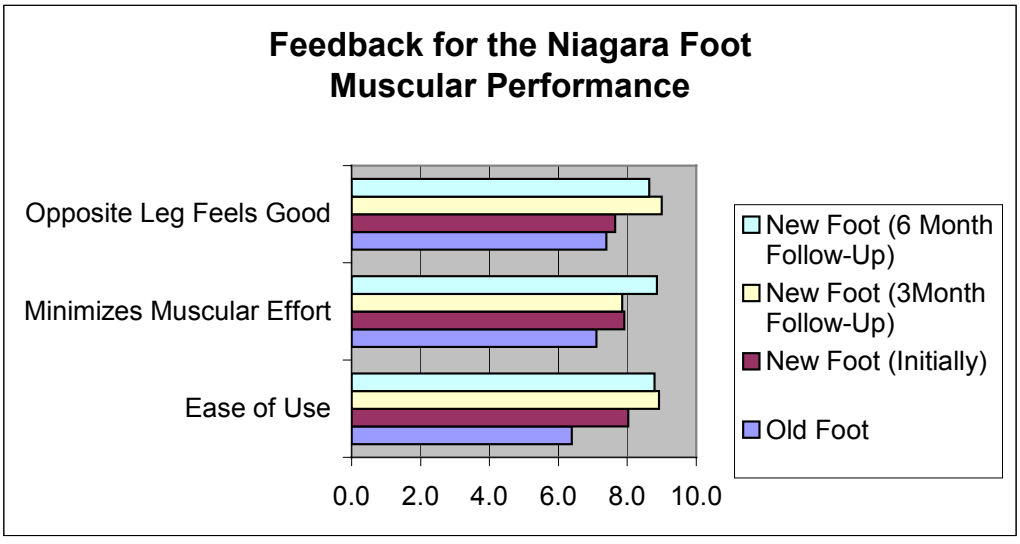

Figure 3: Average results from questionnaires given to the patients using the Niagara Foot, regarding muscular performance.

PATIENT COMMENTS

In the original fitting, it was observed that patients appreciated the biomechanical differences of the Niagara foot compared to the SACH design but were concerned about the stability of the foot. In addition, there was concern regarding the appearance of the foot.

Comments from the 3-month follow-up (Figure 4) tended to focus on aesthetics and practical aspects of the design. A majority related to the cover and its ability to fit in a shoe, as well as its tendency to fill with water. Other comments related to the anterior placement of the connection between the foot and pylon that catches debris in the field. A significant concern regarding the flexion of the heel during heavy loading reflects the scoring pattern for these parameters in the questionnaire results for dynamic performance.

The concern about stability has changed as the patients use the foot for longer and become more used to it. As shown in the comments from the 6-month follow-up (Figure 5), most patients (14 of 16) said that the foot is just as stable as the foot they were using before and is just as comfortable or more comfortable than their other foot.

Most patients (14 of 16) also commented that they became used to the foot quickly, most within a week of the trial. However, one patient expressed difficulty in this regard.

Other comments were consistent with questionnaire scores in terms of toe off, muscular effort and ease of use. Of note is a concern with walking on muddy or uneven ground expressed in 6 of 16 patients. These comments likely reflect the lack of apparent stability due to a flexible heel, covers that collect water, and protrusions at the foot-pylon interface. In addition, attention should be directed to studying motions of the foot around the longitudinal axis (pronation and supination) during activities of daily living.

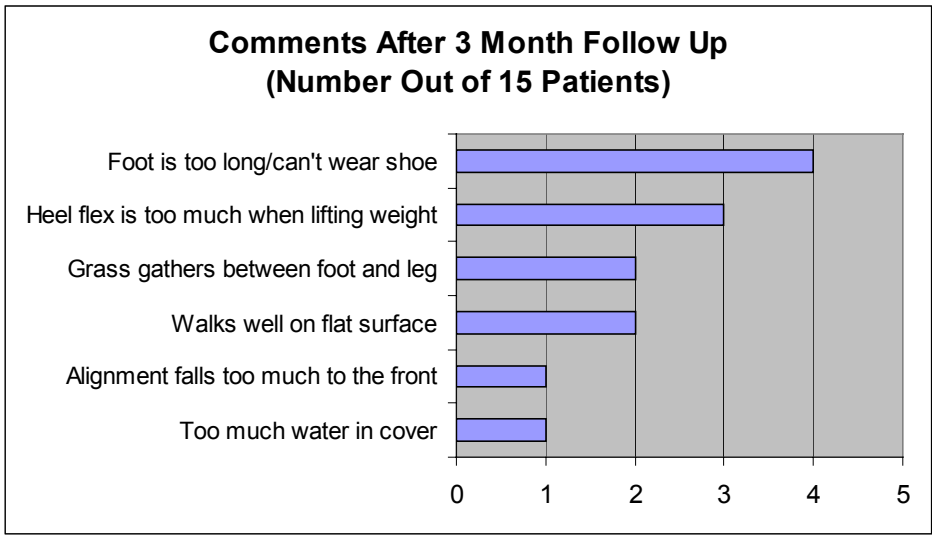

Figure 4: Comments after 3 month follow-up.

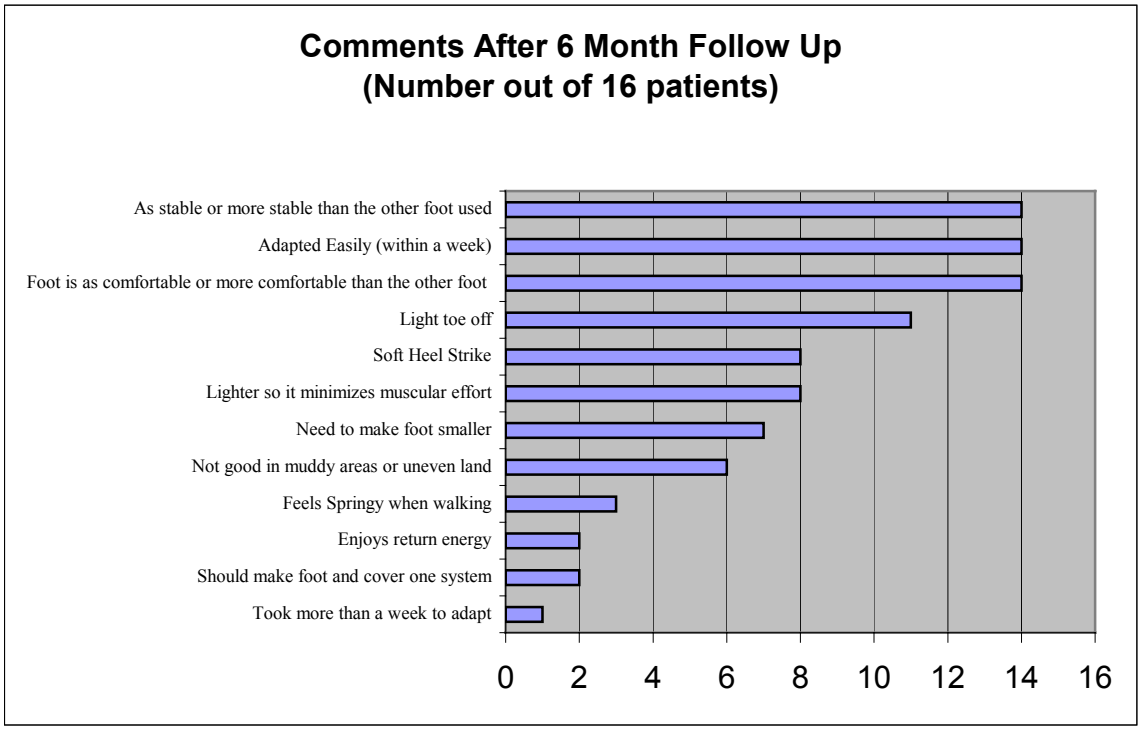

Figure 5: Comments after 6 month follow-up.

PHYSICAL INSPECTION RESULTS

The results of physical inspections by Aranyaprathet Hospital prosthetists at three months and observations made during the six-month visit are compared in Table 4. The data indicate when specific observations were first recorded and these are summed to provide a cumulative total.

The keel showed no signs of significant damage at six months. Non-structural surface cracking and scratching was observed in three specimens, as shown in Figure 6. These effects are likely due to the presence of sand or debris in the cover acting as abrasive (third body) wear elements. A second surface feature was a characteristic inclusion in four of the Delrin ST components (Figure 7). This is likely an artifact of the injection molding process that was not present during the fabrication of the Delrin 100P components. Contact wear was observed in six components at the interface between the upper section and the midfoot (Figure 8). This is a feature also observed in cyclic testing of the component, however, some components had more extensive damage due to the presence of additional third body wear.

Cover tears were a consistent observation, totaling seven to date. It is likely that the lost covers were torn as well. As shown in Figure 9, the cover tear is longitudinal and forms at the widest point of the upper section, at the back. This is likely caused during application or removal of the cover when the foot is attached to the pylon.

In the original fitting of the foot, all modular systems were provided with a counter-rotation screw or pin (Figure 9). None of these had failed during this period.

At three months, five failures were reported that involved other components in the prosthetic system. Two sockets were cracked in the proximal region near the epidcondyles, both exhibiting a similar anteriorly propagating line as shown in Figure 10. Both sockets were made of a low-grade polypropylene, and had thin sections in this region. It is likely that the extension moment during toe off with the Niagara Foot was sufficiently greater than with the original foot in these patients and the socket design was unable to withstand these higher moments. The higher moments may be due to increased activity of the patient or due to an ability to generate higher forces at toe off with the Niagara Foot design.

A similar explanation can be offered for the other three early failures in the distal limb. An example of a modular pylon fracture is shown in Figure 11 showing a fracture consistent with an extension moment that initiated in the posterior region and propagated anteriorly. The material used in this component is a chalk-filled polypropylene that exhibits brittle fracture at a relatively low stress.

Small cracks in the pylon socket interface were observed at both three- and six-month follow-ups (Figure 12). These are made of the same material as the pylons that fractured, suggesting a similar failure mechanism. These cracks were not considered to affect the performance of the system, but may become catastrophic failures with time.

No other component failures were observed after three months. Apparently, the prosthetic systems currently in use are sufficiently strong to withstand the increased demands placed on them by the Niagara Foot.

Comparing the lateral profile of the keel its original shape indicated the presence of any permanent deformation. While no significant deformations were observed, a consistent finding in the Delrin 100P components was an upward deflection of approximately 3 mm at the heel (Figure 12). This pattern is consistent with cyclic test results in the laboratory.

Table 4: Observations made at 3 and 6 months. Numbers are based on the prosthetist comments at 3 months and direct observations made at 6 months.

		New Observations at:		***Total To Date***
		3 months	6 months	
Foot	Failure	_	_	***0***
	Structural Cracking	_	_	***0***
	Surface (non-structural) Cracking/Scratching	_	3	***3***
	Surface Inclusions	_	4	***4***
	Wear	_	6	***6***
Cover	Tear	2	5	***7***
	Lost	_	2	***2***
Socket	Cracking	2	_	***2***
Pylon	Failure	3	_	***3***
Interfaces	Socket/Pylon Cracking	1	1	***2***

Figure 6: Non-structural surface scratching. These effects are likely due to third body wear from sand or debris trapped in the cover.

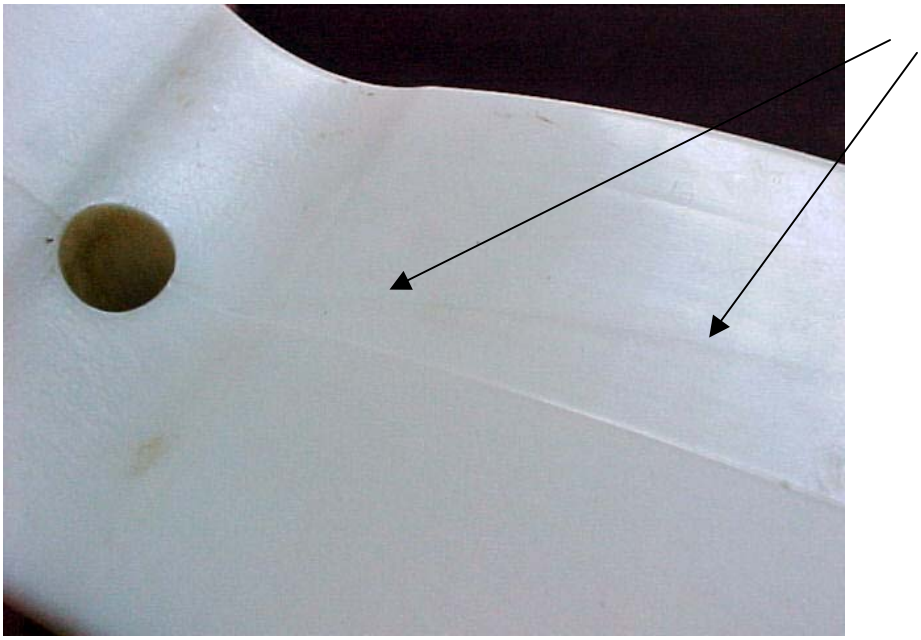

Figure 7: Surface inclusions. A characteristic demarcation line extended from the toe to the pylon bolt hole in 4 of the ST specimens.

Figure 8: Wear. Worn regions were observed at the contact point between the upper section and the midfoot. In some cases this was exaggerated by third body wear.

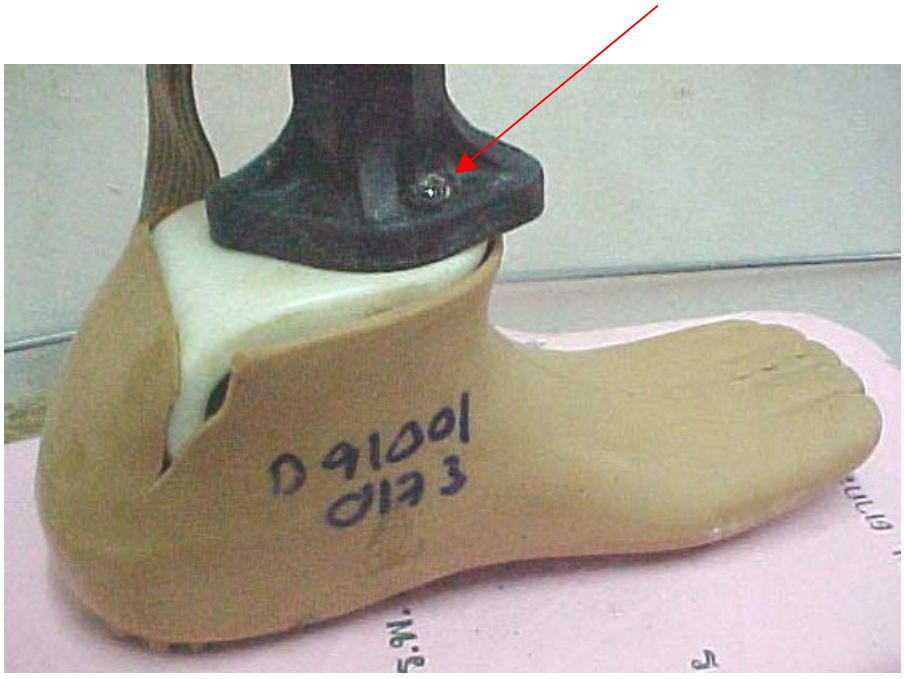

Figure 9: Cover tear. Typical pattern of tear observed in covers. Note counter-rotation screw at the arrow.

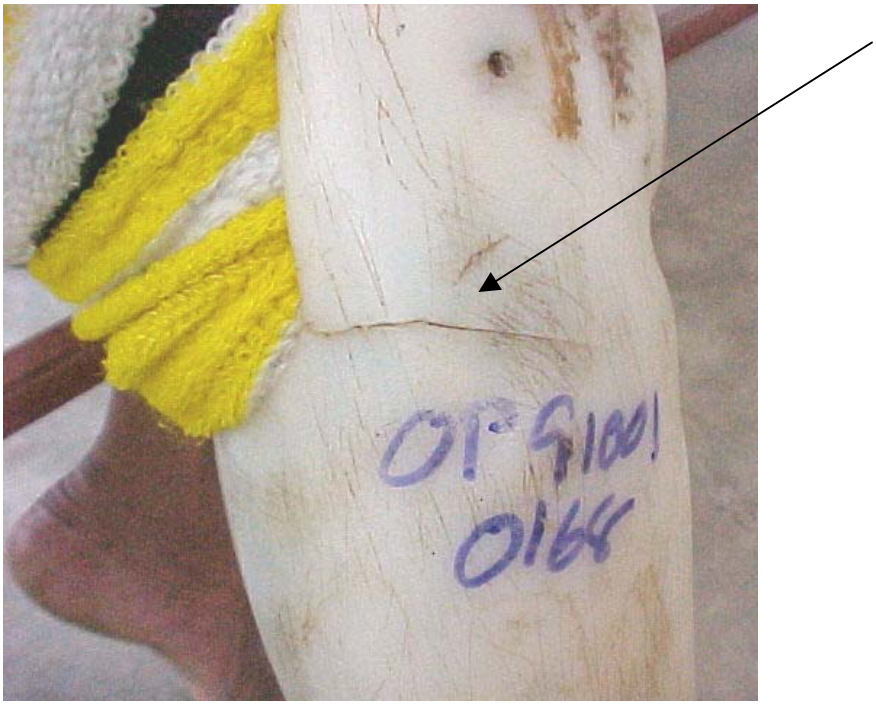

Figure 10: Socket cracking. Two sockets exhibited cracking in the proximal region near the epicondyles. In both cases the crack progressed anteriorly.

Figure 11: Pylon failure. Three cases of distal limb failure were reported at 3 months. The crack is in this modular pylon is typical of high bending stresses in this region.

Figure 12: Socket-Pylon interface cracking. A vertical crack is apparent at the connection.

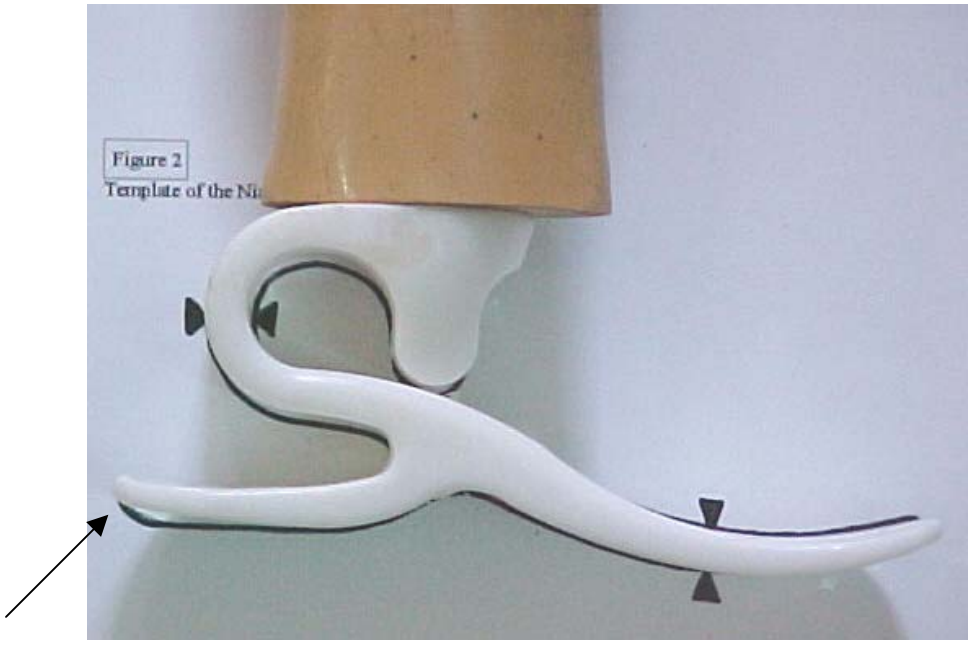

Figure 13: Comparison of lateral profile to initial shape. Minimal permanent deformation was observed as an upward deflection of the heel.

PERFORMANCE TESTING RESULTS

Fourteen patients underwent 15-m walking tests using the Niagara Foot. Of these, 9 also walked using their original SACH foot for comparison. The means and standard errors for walking speed (velocity), cadence (steps/min) and stride length are shown in Table 5. Also shown are the comparative results from Potter (2000) on five North American patients.

The data are similar for both studies, but the Thailand cohort has a trend toward a faster gait and a higher cadence. Stride lengths are nearly identical for both groups.

There is no significant difference between the Niagara and SACH Feet in walking speed, although there is a trend to a greater velocity in the Potter study. Of note is the consistency in both studies for a slower cadence and a longer stride length for the Niagara Foot. A longer stride length suggests a longer duration of stance on the prosthetic foot and an improved confidence in use of the device. As such, the gait may also be more efficient gait in the case of the Niagara Foot. However, more detailed studies are required to verify these preliminary results.

Table 5: Gait Performance for Niagara and SACH Feet. Data from Potter (2000) are used for comparison. Mean values are shown. Numbers in parentheses are standard errors of the means.

		Velocity (m/s)	Cadence (steps/min)	Stride Length (m)
Potter Study n=5	**Niagara**	1.11 (0.04)	101.5 (2.2)	1.31 (0.04)
	SACH	1.06 (0.05)	102.7 (2.0)	1.24 (0.04)
6-month follow-up n=9	**Niagara**	1.19 (0.03)	104.2 (1.4)	1.37 (0.02)
	SACH	1.19 (0.03)	106.2 (2.8)	1.34 (0.03)

FIELD OBSERVATIONS

The purpose of the field observation was to determine typical activities of daily living for the sample population and to compare these to the design and testing activities for the foot.

The two patients observed were both male, one a farmer and the other a barber. The farm of the third patient was observed, but she was not present at the time for demonstration purposes. All patients lived in rural dwellings characterized by rugged uneven pathways and the requirement for stair climbing to reach the living area (Figure 14).

The barber worked in a standing position on an uneven concrete floor for extended periods (Figure 15). There was a minimum of load bearing, but a significant requirement for stability while standing. The patient did not wear a shoe with the Niagara Foot.

The farmer primarily used a "tractor" for all activities. As shown in Figure 16, the device is motor-driven, but guided by the operator. A trailer can be mounted on the tractor to pull loads. In order to mount a plough blade, the trailer must be removed by lifting it at the pin connection (Figure 16a). The tongue weight exceeds 75 kg. During plowing, the downward reaction force at the tractor handles exceeds 50kg (Figure 16b). Under these conditions, the dynamic loads exceed those recommended in ISO Standard 10328 for cyclic testing. In addition to the high loading, there is a need for stability since the tractor is used principally on uneven ground.

These observations clarify patient comments regarding a need for stability while standing and while undergoing loading on irregular surfaces. This was consistent with the observations made at the farm of the third patient. This was a small animal farm requiring the negotiation of a number of pens while carrying feed and other materials (Figure 17).

Figure 14: Typical rural dwelling observed. Note the presence of irregular pathways and the need to use stairs to reach elevated living areas. .

Figure 15: Barber. The workplace requires extended periods of standing on an uneven concrete surface. While loading is low, stability is a concern.

Figure 16: Farmer. The primary device used is a motorized "tractor". **(a, top)** The trailer can be removed or attached by a pin connection. **(b, bottom)** When plowing, the operator must exert an upward reaction force while walking on uneven ground.

Figure 17: Small animal farm. The workplace requires negotiating among animal pens while carrying feed and other materials.

CONCLUSIONS

The biomechanical advantages of the Niagara Foot compared to the SACH foot were evident in initial trials and continue to improve with time. Patients are able to detect and appreciate the performance offered by this design, 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 compared to the original SACH foot in patients.

The flexibility of the heel is a concern for some patients. Increased flexibility under load and during standing suggests to some a lack of stability for activities on uneven terrain. Some consideration should be given to providing increased heel stiffness in these cases.

Studies of patients during activities of daily living emphasize the need for a stable heel strike. Furthermore, the magnitude of peak loading for many patients may exceed the values currently used for testing under ISO Standard 10328.

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. Furthermore, design specifications for compatible sockets and pylon systems should be developed in conjunction with suitable testing methods for BK devices. ISO Standards are not available for this purpose.

The Niagara Foot keel is performing as expected from laboratory testing. There are no failures, a limited amount of wear in contact regions and a small permanent upward deformation in the heel region. In the next phase of manufacturing, the cover will be redesigned to reduce the tendency to rip, retain water, and make it difficult to fit into athletic and dress footwear.

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