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Niagara Foot Trial

Overview of 1 Year Follow-up Visit

A final detailed report outlining results of the 1 year Niagara Foot follow-up study will be forthcoming, once the data analysis is performed by researchers at *Queen's University* in conjunction with *Niagara Prosthetics and Orthotics* and the *Canadian Centre for Mine Action Technology*.

Project 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. In January 2003, a study team from Canada visited Aranyaprathet hospital to complete the study with a final visit.

A final report outlining the results of this study will be forthcoming upon completion of detailed data analysis.

Summary of Biomechanical Results

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.

Preliminary results from the one-year visit indicate consistent findings with the initial and six-month visits. The durability of the foot was reconfirmed with no failures present at the one-year mark. Limited wear marks were present in contact regions and minor yet permanent deformation was evidenced at the top of the foot and at the toe region was present. Also consistent with the six-month mark, rips were found on the foot cover of many patients. In the next phase of the project, the cover will be redesigned to reduce the tendency to rip, retain water, and make it easier to fit into athletic and dress footwear.

Summary of Patient Questionnaire Results

Each patient answered two questionnaires on the foot. The first ask to rank the comfort, dynamic performance, and muscular performance of the foot compared to the prosthetic foot they used prior to trialing the Niagara foot. The second questionnaire asked a series of questions related to the general usage of the Niagara Foot, for example how many hours the foot was worn and for what activities.

A quick scan of the answers to the survey questions indicates that, 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. They would like to see improvements to the cosmesis of the foot cover and have some modifications to the shape of the foot to allow it to fit more easily into a shoe.

Overview of Niagara Foot Trial Timeline and Activities

Visit	Number of patients	Items donated	Number of prosthetic feet installations	Activities that occurred during visit
Initial Trial (November 2001)	20 patients recruited 15 patients accepted (13 male, 2 female)	20 prosthetic feet and covers (10 left, 10 right) 2 specialized prosthetic feet with treads Tools(including Allen key set, caliper, tape measures, connecting bolts, etc.)	15 prosthetic feet and covers. 5 feet and covers left behind	Patient Fittings completed Patient Questionnaires completed
Mid Trial (May 2002)	14 patients (2 patients lost to follow-up, 2 new patients included)	none	none	Foot , foot cover, and socket mechanical evaluation completed Patient Foot and Socket Questionnaires completed Prosthetist Foot and Socket Questionnaires completed Walking performance test completed Off-site visit occurred
Final Trial (January 2003)	14 patients (12 male, 2 female),	16 prosthetic feet and covers (8 softer keels, 8 harder keels).	2 patients had their Niagara feet replaced to give them a harder model. 3 new covers were installed to replace ripped covers. 1 new patient fit with Niagara Foot (not to be included in the study). Remaining items left behind.	Foot , foot cover, and socket mechanical evaluation completed Patient Foot Questionnaires completed Prosthetist Foot and Socket Questionnaires completed Walking performance test completed Off-site visit occurred