# A SYSTEM FOR REAL WORLD MONITORING OF PROSTHESES AND FOOTWEAR

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**Abstract: The problem the EU sponsored Real-Prof project [1,2] seeks to address is that there is no means of scientifically monitoring the performance of therapeutic footwear and lower limb prostheses in the real world. This prevents the early detection of problems under the sole of the foot or on the stump which lead to ulceration, and potentially amputation. Also, clinicians prescribing the footwear or prosthesis and designers of these devices currently have no means of monitoring the performance of the device once fitted, which is a prerequisite for treatment improvements[3]. This paper details the progress in this project so far.**

## Introduction

Real-Prof is an EU Framework 5 project, which started in January 2003. The aim is to develop technologies for monitoring the health of lower limb amputees and patients with orthotic footwear. The project involves 8 partners from the UK, Ireland, Holland, Iceland and Israel, and is being led by the University of Salford.

The core idea is to identify tissue deterioration in an amputee's stump or in a patient's foot before it progresses too far. The importance of this is clear from the following statistics. There are some 600,000 prosthesis users and 2.4 million therapeutic footwear users in the EU. Of the worldwide diabetes population of 150 million, 15% will at some point have foot ulceration (Figure 1), which can lead to amputation of the foot. The average cost of a 2-year programme of care for each ulcer is 29000 Euro.

The goal is to deliver pre-commercial prototype systems which can monitor patients in real-time, in their everyday life, and transmit data to clinics via secure wireless communication. In this way clinical intervention can occur as soon as problems develop rather than being delayed until the patient's next routine visit to the clinic. Sensors will be integrated into the shoe or prosthesis socket to measure skin pressures, gait motions and other physiological parameters. The principal objective of the Real-PROF project, therefore, is to perform the necessary research, development and validation for an advanced intelligent personal health system integrated with prostheses and footwear. The system will collect and interpret previously unavailable data from prostheses and footwear, and present these data to clinicians and designers of prostheses/footwear. The system will be built around three key elements - new micro-scale, low energy sensors mounted in, or on the prosthesis or footwear, wireless telecommunications, and novel data interpretation tools.

Figure 1: Typical foot ulcer

Data will be pressure, oxygen saturation and activity from a prosthesis socket (from EU funded MAPS project [3]), and vertical and shear forces and motion from the footwear. These data sets will be sent wirelessly over a cellular network to a central server where intelligent decision support tools will facilitate early illness detection and timely and targeted allocation of health care resources. This paper will describe the work done so far in the development of the footwear hardware system and the data processing tools. The system will provide intelligent decision support systems


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to enable early illness detection and timely and targeted allocation of health care resources.

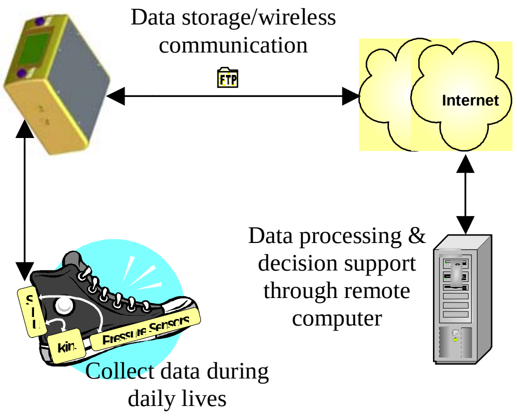


Figure 2: Overview of RealProf system

**System Overview**

Figure 2 shows the proposed system for therapeutic footwear. The prosthesis system is similar except that a different sensor set is used. A Sensor Interface Unit (SIU), which is an integral part of the shoe or prosthesis, provides signal conditioning, analogue to digital conversion and serial communication with the Data Link Unit (DLU), which is worn on the patient's belt. In a future commercial system, it is envisaged that the DLU would be integrated with the patient's mobile phone/PDA, rather than being a separate unit. The data is then transmitted to the clinic's computer system via cellular wireless communication and the internet.

*Sensors*

Low cost, low energy, stable sensors have been researched and developed that will allow the loading at the foot-shoe interface (i.e. the sole of the foot) to be measured over prolonged periods outside the laboratory environment. The force sensor developed in Real-PROF is unique in that it measures not only vertical forces but also shear forces in two directions. These forces are believed to be critical in the development of solutions to clinical tissue problems under the foot, such as ulceration [4,5]. The force sensors are embedded in specially designed in-soles inside the shoe.

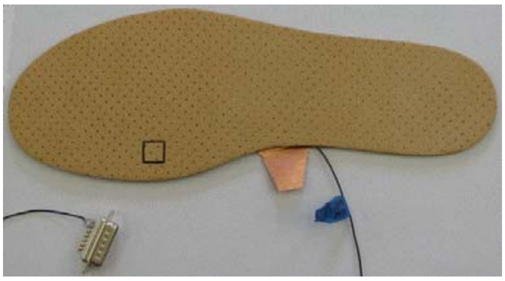

Figure 3: Tri-axial Force sensor from University of Kent located under the 1st metatarsal head

Miniature motion sensor technology has been researched and developed for this application, allowing lower limb and foot motion to be monitored over prolonged periods. The motion sensor provides information on the timing of walking events, such as the time the heel strikes the ground, the foot leaves the ground, stride length, and walking speed. These are critical activity measurements and important in the context of the force data collected [5]. The kinematic sensors are mounted in a box on top of the shoe.

Figure 4: XSENS' MT9 Inertial Measurement Unit (IMU) located in heel cavity

*Sensors Integration Unit (SIU)*

The SIU links both sets of sensors with the CDLU). The SIU contains the charge amplification and A/D conversion circuitry for the force sensors and the digital bus circuitry [6]. The digital bus protocol utilised for the sensor systems is called the Xbus, a proprietary system developed by Xsens [7]. In short, it is a protocol with a 'Master Unit' controlling multiple 'Slave Units'. The CDLU will host the Xbus Master Unit while the force sensors and kinematic sensors will connect to the slave units. Signals from both sets of sensors are transferred to the SIU via cables. Since the kinematic sensors provided by Xsens provide digital outputs and it utilises the Xbus protocol, no signal conditioning is required for the kinematic sensors.

The force sensor outputs, however, require an amplification stage, A/D conversion and connection to an Xbus slave unit before data is in the correct format for transfer to the CDLU. The SIU is realised as a 48mm x 33mm motherboard with 2 48mm x 17mm daughterboards attached.

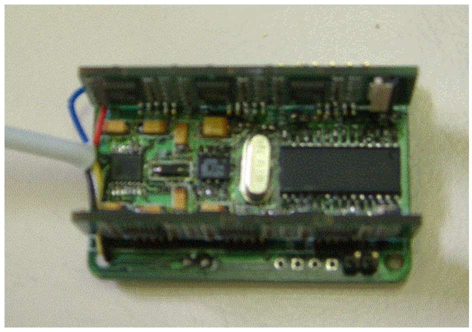

Figure 5: Motherboard with daughter boards attached

*Central Data Link Unit (DLU)* **-**

The CDLU contains the

- User Interface
- Internal Rechargeable Battery – the CDLU provides power to the SIU and the sensors
- Removable Recording Media for data storage
- RealPROF Archive interface – FTP
- SIU Interface - XBUS Protocol Master Unit

*Intelligent Data Processing*

The data will be interpreted and presented to the user groups according to their needs. For the clinician, data interrogation techniques will be used to define instances when conditions at the shoe/foot or prosthesis/stump move outside normal boundaries for that patient. For the designers, data processing will be researched and developed that allow access to data describing material and product performance, and data that influence product specifications and design. Current methods for the analysis of walking data still rely heavily on interpretation by specialists (gait analysts). Real-PROF will gather new and large real world data sets, requiring innovation in the processing and interpretation of gait data. Real-PROF will apply advanced software techniques in the areas of:

- Data enrichment – adding to the collected data
- Clinical decision support systems – detecting normal and abnormal data using the patterns of data, relationships between different data, and vast databases for each patient.

**Data processing**

Advanced data processing algorithms are being developed, the aim being to provide patient alert, clinical decision support, and data for design and research purposes. Data processing can be viewed as two distinct problems, data enrichment and decision support. Data enrichment uses the raw sensor data to derive new, more useful data. Decision support uses the raw data and the derived data to identify normal and abnormal patterns, and thereby provide clinically useful information. Figure 6 shows how these two aspects interact.

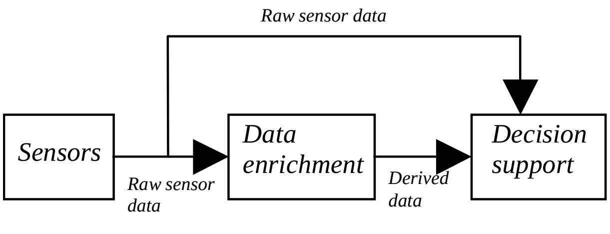


Figure 6: Interaction between sensor data and decision support

The algorithm development is in its early stages and only data enrichment has been considered to date. The aim is to look for correlations between the raw sensor signals (input data) and traditional gait laboratory measures or the activity being undertaken (output data). Where good correlations exist, algorithms will be developed to estimate the output data from the raw sensor data.

Figure 7 describes the aim with regard to traditional gait laboratory measures. The idea is to simultaneously collect Real-Prof sensor data and traditional gait laboratory data. Where good correlations exist, the data will be used to develop algorithms which can:

- estimate the motions of the lower limbs (e.g. segment angle time histories) from limited motion sensor data;
- estimate net forces and moments (e.g. ground reactions or stump loads) from the force/pressure sensor data.

If both of these can be achieved, then inverse dynamics calculations could be used to estimate the loads at the joints of the lower limbs.

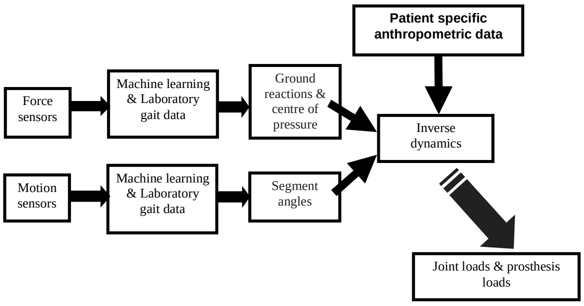


Figure 7: Data enrichment process

Because simultaneous Real-Prof and gait laboratory data has not yet been collected, virtual motion sensor data has been used to enable algorithm development. Data collected in the gait laboratory using a VICON multi-camera motion capture system has been used to generate both input and output data. The input data are the accelerations of the heel of the shoe and the angular velocity of the shoe, for both left and right shoes (sagittal plane only). Figure 8 shows an example of acceleration $\alpha$ of the left foot along the y axis and the corresponding velocity $\omega$ for four gait cycles (all curves are drawn in different colour). This data mimics the signals that would be obtained from accelerometers and a rate-gyro in the heel of each shoe. The output data are the time histories of the lower limb segment angles. Figure 9 depicts two angles $\theta$ for the left foot and shank.

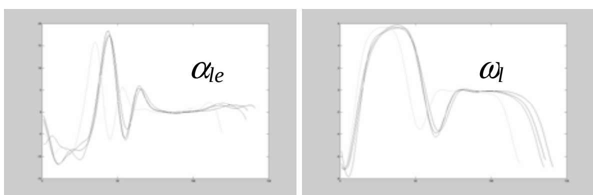


Figure 8: Acceleration and velocity of left foot for four gait cycles


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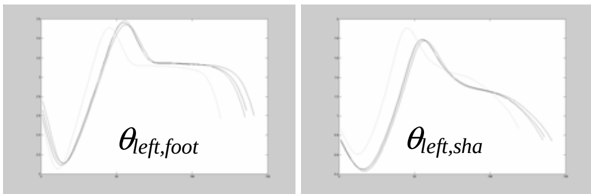


Figure 9. Angles $\theta$ for the left foot and shank

Experimentation with artificial neural-networks [8,9,10] is ongoing. The aim is to use a network, to estimate the segment angle time histories $\theta$, given the virtual sensor data {$\alpha$ and/or $\omega$}. We have already demonstrated that a network is capable of learning the input-output mapping for one gait cycle (training data only). We are currently using data from multiple gait cycles to investigate the mapping of unseen data (separate training and testing data).

**Results**

Initial experiments showed that neural networks perform adequately in the fitting of segment angles from the kinematic data of one specific gait cycle. The success of this task reveals that the sought mapping is a functional one and the relation between kinematic and positional data is predictable for a given cycle. In total, there are six network input signals (two accelerations and one velocity per foot) and seven angle signals.

Results investigating the effect of sensor data reduction, demonstrate that if the neural network is provided with data from only one foot and/or a subset of translational acceleration or angular velocity components the prediction deteriorates. However, by enriching the remaining data (e.g., by a functional expansion of the input signal, such as differentiation) the prediction accuracy can be reinstated. The conclusion is that enriching does enhance prediction accuracy, which means that simpler kinematic sensors can be used, perhaps only providing a few acceleration components, and not angular components as Real-Prof is using.

We have used the following types of networks:

- Multi Layered Perceptrons (MLP)
- MLP with Regularisation (MLP+R)
- Radial Basis Function networks (RBF)
- RBF networks with Regularisation (RBF+R)
- Generalised Regression Neural Networks (GRNN)

Due to noisy measurement there is variability between the cycles and this makes generalisation of the networks a difficult task. All types of networks perform curve fitting of one gait cycle equally well, but GRNN are the most successful in predicting unseen gait cycles. We have tried a large number of different experiments with varying number of training, validation and testing sets. As currently we only have data for one person (with multiple cycles), we train the network with one to two cycles and assess the prediction accuracy of each of the networks (with different parameters/topologies) for each of the seven available angle signals.

Figures 10-12 exemplify the learning process. Figure 10 shows the results of predicting the left foot angle using a RBF network. Training is using one cycle (shown first in the graph) and testing the subsequent three ones. The correlation coefficient $\rho$ was *0.95*. Figure 11 shows the same experimental setup using MLP+R, where $\rho$*=0.97*. Figure 12 contains the results for the GRNN runs, where the value of $\rho$*=0.996* was obtained.

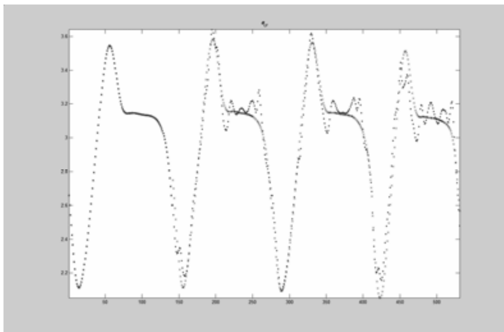

Figure 10: Prediction of the left foot angle using a RBF network

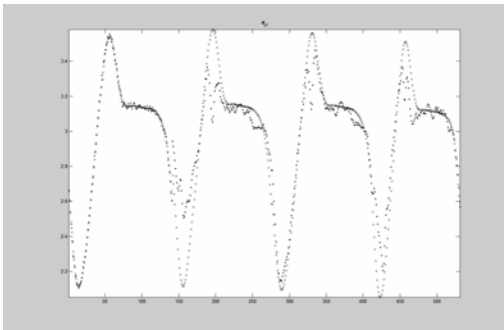

Figure 11: Prediction of the left foot angle using MLP+R

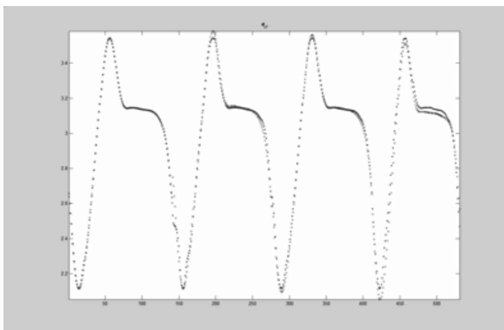

Figure 12: Prediction of the left foot angle using GRNN

**Conclusions**

This paper has presented the architecture of an in-shoe real-time measurement system for performance


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monitoring of therapeutic footwear. The significant parts of the system have been described while the initial data processing algorithms and results have been presented. The hardware system is currently being evaluated and will be tested in trials in the near future. Overall results for the data processing obtained so far are very encouraging yielding high quality fitting errors for all networks and for all angle signals. Furthermore, data enrichment is shown to be feasible, and this is highly beneficial to the sensor reduction task. GRNNs proved to be better in generalising unseen gait angle patterns, but all networks performed with high correlation coefficients and small normalised root mean square errors.

It is difficult to judge at the moment though, whether this observation will persist with the actual Real-Prof data, since we currently only have virtual acceleration data, which is less noisy than the likely accelerometer based data. Nevertheless, the success with virtual data measurements proves that this should be the case, unless noise effect over-contaminate the data streams. Another important issue is the inter-subject generalisation. Predicting the output of unseen individuals is a very important issue which we plan to address in depth when more data is obtained.

## Acknowledgements

This work has been funded by the EU Framework V Information Societies Technology (IST) Programme(Contract no.: 38429).

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