1. Publishable summary

1.1. Context and objectives

Disabling foot and ankle pain is common; it impacts negatively on health related quality of life, and it is has major cost implications on health systems across Europe. Estimated prevalence in Europe suggests approximately 200 million citizens suffer and this is set to rise in an ageing society with increasing chronic long term conditions. Cost is currently estimated at €312 million per annum across European health services. Foot and ankle orthoses are an effective treatment for these conditions. However, the market is dominated by low cost mass produced products, craftsmanship built customised devices with delivery times usually higher than 10 days, and a limited range of computer-aided design and NC-milled manufactured products. ***The objective of the A-FOOTPRINT project is to develop novel foot and ankle orthoses which are personalised for shape and biomechanical function and can be ready for patient use within 48 hours. The goal is to achieve improved fit and comfort, functionality, aesthetic appeal and ease of use with better clinical and cost effectiveness over state-of-the-art products.*** Innovative CAD tools will be developed and combined with rapid manufacturing to create complete geometric design freedom. This will be coupled with step change advances in personalisation by developing individual patient data from gait analysis and medical images to inform the design process, aided by biomechanical simulation to optimise functionality such as joint stabilisation and pressure distribution. Rapid manufacturing techniques will be used to develop novel customised orthotic components such as living hinges, variable stiffness and fine resolution cushioning to enable improved personalised function. Setting new industry standards, prototype devices will be evaluated by near pharmaceutical industry level controlled trials to further improve product knowledge. This highly integrated, multidisciplinary project will make a significant impact on the health-related quality of life and well-being of EU citizens. The Consortium comprises leading orthotic and enabling technology SME's, clinical and academic research centres and large enterprise. The project will enable the SME's to become international leaders with strong competitive advantages. A-FOOTPRINT will directly benefit SME partners in the following ways-

- Impact the high value added global market for personalised ankle and foot orthoses; in a market with high growth potential due to aging populations, increased incidence of foot and ankle problems, and strong consumer focus on personalised foot care products.
- Result in the development of cost-effective personalised ankle and foot orthoses which will have a significant impact on health related quality of life and wellbeing.
- Produce through advanced technology and new knowledge creation orthotic devices.

The project, organised as nine integrating work packages, is designed to deliver step change research involving patient diagnostics and computer-aided design (CAD), biomechanics, material science, and rapid manufacturing. Rapid Manufacturing will incorporate enabling technologies such as CAD tools in order to provide complete geometric design freedom. Optimisation for personalised function combined with embedded sensing technology, and evaluation by robust clinical tests will lead to the successful development of new knowledge-based products.

1.2 Work performed and main results

The work performed within the first 36 months of the A-FOOTPRINT project has been distributed among **six** main RTD work packages. The ***key objectives*** for the reporting period can be summarised as:

- In **WP2**, 1) to develop a Patient Information System, and 2) to produce highly personalised anatomical and biomechanical datasets, and 3) to benchmark and select a digital 3D scanning protocol to capture ankle/leg/foot geometry for CAD orthotic design.
- In **WP3** and **WP4**, 1) to create a scalable kinematic and kinetic model of a normal foot, consisting of all major bones, joint and ligaments and muscles which can be loaded and driven kinematically using plantar pressure data for normal and pathological conditions (AnyBody Modelling System, AnyBody Technology), and 2) to develop that model within a multi-body, finite element software package as prerequisites for orthosis modelling and simulations (MADYMO).

- In **WP5**, 1) to define co-created specifications for a Personalised Orthosis Design (POD), CAD/CAM system, 2) to develop and test a prototype CAD POD system and test with end-users, 3) design a minimum of two new, innovative orthoses.
- In **WP6**, 1) to define facility specifications for rapid manufacturing for ankle-foot and foot orthoses, 2) to define sensor specifications for embedded use in personalised orthotic designs, and 3) to define manufacturing process evaluation and development specifications for a rapid manufacturing facility benchmarked against state-of-the-art, 4) to test the performance of the proposed manufacturing solution by manufacturing existing and novel orthotic designs, and 5) to create a dedicated orthotic manufacturing cell (pilot factory) within an SME production environment.
- In **WP7**, 1) to develop an evaluation framework to test prototype ankle-foot and foot orthoses for safety, mechanisms of action and efficacy, 2) to perform pre-clinical, phase I and phase II clinical trials on prototype ankle and foot orthoses, and 3) to produce a A-FOOTPRINT business model.

In this second reporting period the majority of these objectives have been completed, with a delay only to the development of the MADYMO model (WP4).

In **WP2**, the Patient Information System database was successfully designed, developed and pilot tested. SME partners and other stakeholders were extensively involved to define user-relevant input/output data, interface features, and access and storage capabilities. Other enabling technologies developed within the project are currently being integrated with the A-FOOTPRINT Patient Information System (A-FIS). The A-FIS system is the central information system capturing patient information, diagnostics and assessments, orthotic CAD designs and product information and workflow and is accessible via cloud computing networks. The result is at an advanced stage of commercial exploitation readiness and partner RSS are leading exploitation activities with FON.

Following ethical approval, the clinical centres in Glasgow and Maastricht have successfully completed the personalised anatomical and biomechanical datasets from healthy adult subjects and patients with common foot and ankle impairments. Motion-capture techniques were developed and employed to capture bone movement in fine detail during walking and related activity, coupled with force and pressure measurement and electromyographic muscle activity. These same subjects underwent medical imaging (CT and MRI) to build 25 highly detailed anatomical models which included all the foot and ankle bones, major muscles, and soft-tissues including ligaments. In addition surface scans were obtained in 3D employing an agreed technique following a successful evaluation and benchmarking exercise. These datasets comprised the input for the musculoskeletal and orthotic modelling work undertaken in **WP3** and **WP4**.

In **WP3**, excellent progress has been made to develop a scalable kinematic and kinetic model of the foot. Working in the AnyBody Modelling System, the first stage of model development required researchers from AnyBody Technology (ABT) to successfully define the kinematic links between the bones including the centre of rotation and orientation axes which were optimised using the subject-specific motion capture kinematic data generated in **WP2**. Kinematic rhythms for major structures have been successfully defined. The geometry of three-dimensionally reconstructed bone structures have been successfully scaled via morph-based scaling. The second stage of development was successful in adding complex soft-tissue structures to the model including extrinsic and intrinsic muscles. Major foot ligaments have been added and refined based on subject-specific medical imaging data. Joint rotations and muscles actions have been predicted and successfully validated against published data. For the third stage of model development, RSS, and ABT worked together to implement plantar pressure data to drive the foot model. Progress here has started to open up real opportunities to employ modelling in the clinical environment to aid orthotic design and use. Modelling pathological foot and ankle conditions has progressed well. The results in WP3 have strong added-value due to the commercial exploitability of the new foot model for biomechanical simulation activity beyond the scope of orthotic modelling. In **WP4**, the basic MADYMO model has been developed and task meetings conducted to link the dataflow from WP2 (personalised biomechanical data sets) and integration with the AnyBody Modelling system in respect to models and muscle

simulations to drive the forward dynamic analyses. Further work is required to refine the model, to develop a dataset of impaired/pathological foot and ankle conditions and to develop the numerical shoe and orthosis model.

In **WP5** excellent progress has been made towards the development of a Personalised Orthotic Design (POD) CAD/CAM system, one of the major objectives of the A-FOOTPRINT project. The RTD activity started with a number of task meetings and wide consultation with SME and clinical partners to define the user specifications and Design Workflow. The alpha version of the software was successfully developed in the 3-Matic platform, working with SME partners to develop a user-friendly interface and automated functionality. Prototype designs have successfully been created for ankle-foot orthoses and foot orthoses, including novel and highly innovative features. Design file output/input compatibility with rapid manufacturing systems has already been demonstrated and verified through the successful manufacture of prototype devices. Success has also been achieved for development of a co-creation design process in **WP5** to exploit user customisable features that emerge as part of the exploitation of design freedom in additive manufacturing. These will the enable clinical services to move beyond the usual restricted list of varying personalised devices by colour or pattern for example.

Work conducted in **WP6** related to Rapid Manufacturing has been highly successful in achieving the key objectives. The *Manufacturing Facility Performance Specification* has been successfully benchmarked along with on-site and laboratory testing quality assurance procedures including benchmark parts specifically for rapid manufacturing technologies. Work proceeded to complete a *manufacturing process and development framework* after observing and benchmarking the facilities and processes undertaken by the SME beneficiaries. Following this, rapid manufacturing alternatives were evaluated focusing on central manufacturing facility based approaches including stereolithography, selective laser sintering, fused deposition modelling, and 3D printing as well as desktop type manufacturing equipment. The outcome of this work led to the selection of a rapid manufacturing technology to go forward with. Finally, a manufacturing productivity evaluation scheme was developed based on ankle-foot and foot orthoses considering time, cost, flexibility and quality. Within this work package specifications were successfully developed for embedded sensors based on commercially available and novel devices. Several of these options have been successfully embedded in novel prototype devices for bench and field testing. Successful manufacturing trials of prototype ankle-foot and foot orthotics have taken place at the pilot factory facility and these products are currently under evaluation in pre-clinical and clinical trials as detailed in WP7.

WP7 successfully developed a product evaluation framework based on the clinical and laboratory-based evaluation of product mechanisms of action, safety and effectiveness. This framework developed semi-quantitative and qualitative assessment schedules and exploited the developments in WP2 regarding personalised biomechanical datasets. It has enabled biomechanical techniques to be adapted and further developed to quantitatively assess ankle-foot and foot orthotic function *in vivo*. Pre-clinical testing has successfully characterised the properties of sintered orthotic materials to ISO standards using mechanical bench tests and FE analyses. Phase I and II trials have commenced (with full ethical approval) for prototype AFO devices for stroke patients with drop-foot and FO devices for patients with flat foot and metatarsalgia. The *A-FOOTPRINT* business model continues to be developed and has advanced following a successful exploitation strategy seminar identifying the key results and their commercial readiness for exploitation. Work continues to develop and improve the integration of the project results.

In **WP8** excellent progress has been made to develop the demonstration pilot factory facilities in line with work conducted in WP6. Rapid manufacturing facilities have been installed, commissioned and are now producing prototype orthotic products for evaluation. Major activity is in progress to plan and organise the major demonstration activity for the project in March 2013 with major stakeholders from across Europe attending PCK –based pilot factory for demonstration of the integrated solution. Other major demonstration activities include the internationally leading orthotic trade fair in Leipzig in May 2012 and the EC Industrial technologies 2012 meeting in Aarhus in June 2012.

1.3 Expected final results and their potential impact and use

A summary of the expected final and tangible results of the *A-FOOTPRINT* project are:

- To develop a software-based Patient Information System.
- To develop Computer Aided Design (CAD) software for personalised ankle-foot and foot orthotics.
- To develop design optimisation software routines for personalised ankle-foot and foot orthotics.
- To evaluate and benchmark Rapid manufacturing techniques for personalised ankle-foot and foot orthotics.
- To integrate these results to produce a fully integrated orthotic design and manufacturing solution.
- To influence relevant health and policy.

These results will impact the high value added global market for personalised ankle-foot and foot orthoses; in a market with high growth potential due to ageing population; increased incidence of foot and ankle morbidity; and strong consumer focus on personalised comfort devices to aid health and increase performance in sport and leisure pursuits. The results will also lead to the development of personalised orthotic devices which will have a significant impact on health related quality of life for European citizens and produce through new design and manufacturing technologies and orthotic products to be exploited for use among clinical, technical and retail customers, in an SME rich sector.

1.4 The A-FOOTPRINT Consortium

Beneficiary short name	**Beneficiary name**
GCU	Glasgow Caledonian University
BOS	UAB Baltic Orthoservice
UNEW	University of Newcastle Upon Tyne
MAT	Materialise NV
PCK	Peacocks Medical Group Ltd.
FFY	Firefly Orthoses Limited
KHK	Katholieke Hogeschool Kempen VZW
RSS	RSscan International
ABT	AnyBody Technology A/S
MAS	academische ziekenhuis Maastricht
TNO	Nederlandse Organisatie Voor teogepast Natuurwetenschappelijk Onderzoek WITHDRAWN FROM CONSORTIUM – APPROVED BY EC 04/10/2011
FON	Stichting Fontys
JDZ	Junquera y Diz S.L.

1.5 Project website

Further details of the *A-FOOTPRINT* project can be found at:

www.afootprint.eu

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