3.1 Publishable summary

3.1.1 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 AFOOTPRINT 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.

3.1.2 Work performed and main results

The work performed within the first 18 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.
- 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 (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.
- In **WP6**, 1) to define facility specifications for a rapid manufacturing facility 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.
- In **WP7**, 1) to develop an evaluation framework to test prototype ankle-foot and foot orthoses for safety, mechanisms of action and efficacy, and 2) to produce a preliminary market survey.

In this first reporting period the majority of these objectives have been completed, with a delay only to the development of the MADYMO model. Reallocation of work tasks across the Consortium will enable the objective to be completed at 24 months.

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. Following ethical approval, the clinical centres in Glasgow and Maastricht have made excellent progress in obtaining 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 to build 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 obtaining ethical approval for this work, there is a 4 month delay in completing the measurements on the planned 25 cases. However this delay has not prevented the modelling work in WPs 3 and 4 to progress smoothly and on time. Effort on this task will be accelerated between months 18-24 to return the work package to the planned time scale.

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, RSScan, and ABT are working together to implement the use of 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. Finally, work has commenced the process of modelling pathological foot and ankle conditions. 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. The Design Workflow has been developed and continues to be refined. The alpha version of the software has been developed in the 3-Matic platform working with SME partners to develop a user-friendly interface and automated functionality. Prototype designs have already been created for ankle-foot orthoses. 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.

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*. In working towards an *A-FOOTPRINT* business model a market survey tool was successfully developed and used on end users focusing primarily on clinicians within the sector. Using web-based techniques this survey has been embedded in the project website and a snowballing technique initiated to continue data collection over the lifespan of the project and across multiple European health care models.

3.1.3 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.

3.1.4 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
FON	Stichting Fontys
JDZ	Junquera y Diz S.L.

3.1.5 Project website

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

www.afootprint.eu

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