Ankle and Foot Orthotic Personalisation via Rapid Manufacturing

Final Report Summary - A-FOOTPRINT (Ankle and Foot Orthotic Personalisation via Rapid Manufacturing)

Executive Summary:
The manufacture of custom orthoses for the foot and ankle is dominated by subtraction manufacturing techniques based on CNC-milling or hand-fabrication of thermoplastic materials. Single-batch production, particularly larger custom ankle-foot orthoses, is time-consuming, costly, leads to delays in patient-treatment. Hand-manufactured orthoses are difficult to reproduce. Design optimisation beyond orthotic shape is limited, overlooking new capabilities in personalised biomechanical technologies. Such technologies have not been widely integrated within the value chain and subsequently orthotic performance is not verifiable and potential treatment benefits are lost.
A-FOOTPRINT approaches these issues by developing and validating additive manufacturing as a new technology for custom orthoses, supported by new enabling technologies for product design in CAD and functional optimisation using personalised biomechanical models and simulation within the value chain (Figure 1).

The A-FOOTPRINT approach has four central themes:
1. Successful development of emerging additive manufacturing techniques with fully validated performance specifications and processes; demonstration of a pilot factory producing new prototypical orthotic devices based on the selective laser sintering method, including novel features such as varied wall thickness, adjustable/tuneable functional features and embedded sensing. Demonstration of new orthotic product lines, validated from mechanical and clinical trial testing that are commercially exploitable for European customer base.

2. New Computer-Aided design software (Personalised Orthotic Design- POD CAD) to support free-form design capabilities afforded by additive manufacturing with enhanced CAD features yielding a portfolio of prototype ankle and ankle-foot orthoses.

3. Advances in functional personalisation through musculoskeletal modelling to provide new computational techniques for understanding highly complex functional requirements of the foot and ankle and translating these into new and validated orthotic design rules.

4. Technology integration and database management of integrated value chain and corresponding business models for the European orthotic sector.

The advantages of this approach are the capabilities that additive manufacturing give to freeform design and with that the opportunity to develop, manufacture and test innovative orthotics products reliably, at speed and at competitively cost.

The CAD design capabilities are enhanced and offer new design solutions that overcome limitations associated with subtraction manufacturing such as wall thickness, functional components and sensing as well as enhanced opportunities for clinicians, technicians and patients to co-create product designs.

A-FOOTPRINT provides new optimisation capabilities to steadily improve orthotic design based on high-resolution and scalable ankle and foot biomechanical models that are driven by clinically-based foot biomechanical measurements and through that improve further the patient experience and outcome.

Project Context and Objectives:

2.1 Challenges within the current clinical context
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 (see Figure 1.1).

2.2 State-of-the-art of custom ankle/foot orthotic manufacturing
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. Across the European health care systems customised orthoses are handcrafted in SME factories for approximately 75% of patients. Current state-of-the-art is moving towards CAD-CAM systems with various centralised and distributed models ranging from complete office-based solutions to SME factory-based manufacturing. The orthotic SME partners for A-FOOTPRINT came together through a collective motivation to overcome current limitations with CAD-CAM; limitations they alone as an industry are unlikely to solve. Moreover CAD-CAM users find it difficult to understand the technology and in 20% of users production costs increased. Moreover design software is often basic and the product range is limited as manufacturing is restricted to numerically controlled milling of plastic blocks. Finally, state-of-the-art milling creates unsatisfactory levels of waste material which is currently difficult and costly to recycle. Therefore despite improvements in personalised fit, CAD-CAM has failed to
difficult and costly to recycle. Therefore despite improvements in personalised fit, CAD-CAM has failed to advance personalised function. What is clear from SME orthotic companies is that hand-crafted devices can no longer remain state-of-the-art. Techniques such as vacuum forming, machining and hand-finishing produce orthoses that are not reproducible and difficult to verify or control for quality and functionality.

2.3 A-FOOTPRINT approaches to existing challenges

The overall 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.

2.3.1 Additive manufacturing

Solid freeform fabrication techniques produce low volumes of components with low lead times and have now been a commercial reality for almost two decades. From processes which created initial prototype models (known as rapid prototyping) with rather poor mechanical properties for “form and fit” evaluation a wide range of processes have subsequently been developed which exploit layer (additive) manufacturing to deliver one-off or small volumes of component for a wide range of applications. The processes are now mature enough to be used to create components which are functional and in their end-use state (rapid manufacturing), with important medical examples being the production of in-the-ear hearing aid shells, and the use of selective laser sintering to create drill guides for dental surgery. Solid freeform fabrication processes are additive, with material added layer by layer to create a 3D whole and these layer manufacture processes offer some distinct advantages in the creation of components as they offer a high level of geometric freedom in the production of shape, so it is possible to create shapes with re-entrant angles, draft angles are not required, parts with variable wall thicknesses can be created, and there is no need for a split line. This geometric freedom makes the various layer manufacturing techniques very attractive for medical applications. Rapid manufacturing technologies are digital, and must be driven by a CAD model and offer significant advantages in the manufacture of customised and one-off products as they are less sensitive to traditional economies of scale: there is only a marginal cost increase in producing one hundred one off components as compared to producing one hundred of the same component if the volume of the components is the same.

2.3.2 Innovative CAD tools

The design of customised ankle and foot orthoses relies on the skill and experience of both clinician and technicians and these vary across the European markets. In orthopaedics for example many clinicians will not specify design parameters and leave this to the skill of the technician working to the patient’s template or cast. Other clinicians will fully design orthoses specifying choice of materials, density, thickness and regional variation relative to the therapeutic objective, e.g. localised pressure relief. Using anatomical landmarks relative to the template or cast, the shape of the orthosis will be specified for each individual using subject specific details such as foot arch height for a foot orthosis and calf muscle bulk for an ankle-foot orthosis. Paradigms of foot function related to disease states such as diabetes have influenced design features such as inbuilt corrective wedges and pressure redistributing plugs, however, clinicians rarely work to verifiable design rules. Pre-fabricated, non-personalised orthoses are frequently used to provide rapid, low cost treatment. Orthotic designs from the clinician are most frequently written to forms or templates and sent with the cast to the manufacturing centre. Across Europe, computer-aided design (CAD) is an emerging field but with low market use.

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The A-FOOTPRINT approach will integrate for the first time in this field the powerful capabilities of biomechanical modelling with 3D surface scanning and rapid manufacturing to provide complete geometric ankle and foot orthotic design freedom and deliver this in a user-friendly, co-created software environment (see Figure 2.1).

3.3 Functional customisation

Several multi-segment models for the foot and ankle have been proposed and mainly used for the determination of kinematics and use functional segments to model the degrees of freedom of the foot. Up to now a comprehensive description of foot kinematics is lacking and little data is available concerning kinetics. Modelling of the foot with all significant muscles and ligaments has not been resolved to date. Recent progresses in computational biomechanics reveal the possibility to determine the recruitment of individual muscle and their forces. Today, new technologies for simulation of musculoskeletal systems are emerging that allow for the modelling of the mechanics of musculoskeletal systems including active muscle forces as well as passive-elastic properties of tissues such as fascia, tendons and ligaments. This technology represents an obvious opportunity to improve diagnostics of foot dysfunctions as well as the design of foot and ankle orthoses. A major drawback of contemporary numerical models is that they are a representation of what is believed to be the “average” foot. As such models have been developed on the assumptions of simplified geometry, limited relative joint movement, basic ligamentous structures and simplified material properties. This makes them suitable to address generic research issues but of limited value for use in the development of personalised applications. The scalable foot models developed in this project will represent a major advancement contributing significantly towards addressing the SME’s requirements for the development of knowledge-based and verifiable orthotic devices. The A-FOOTPRINT approach will develop high-fidelity, personalised musculoskeletal and finite element models of the foot and ankle far surpassing current state-of-the-art; extend these personalised models to representative diseases of the foot and ankle; and build into these models finite element orthotic models to optimise personalised orthotic designs to a level surpassing state-of-the-art.

2.3.4 Technology integration

Large quantities of data from diagnostic and prescribing processes informs the design and manufacture of custom orthoses. Among end-users there is a requirement to adapt any new orthotic value chain to current technologies including medical imaging, biomechanical analyses and CAD design. These are largely paper-based exercise with estimates that 80% of orthotic prescriptions are incomplete and lead to potential errors in design and manufacture. There are strong motivations in the A-FOOTPRINT approach to provide an integrated digital database solution, that is co-created with SME partners and flexible to embed current enabling technologies datasets.

2.3.5 Building market awareness and business model

Market awareness on the capabilities for additive manufacturing for custom orthotic products is very limited. This problem will be addressed with A-FOOTPRINT by developing and implementing a strategic dissemination and demonstration programme for end-users and other European sector beneficiaries; contributing to European-wide technology platforms and International collaborative initiatives such as IMS; and undertaking a market survey and development of a business model for exploitation of final tangible results. The focus will be on SMEs with the following benefits;

- 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.
Project Results:
3.1 Specific, measureable and attainable objectives
The objectives of A-FOOTPRINT are to improve the accuracy of clinical prescriptions for customised foot and ankle orthoses; to improve the fit and functionality; to significantly decrease manufacture time to 48 hours; to develop a cost-effective, fully integrated orthotic manufacturing solution; and to disseminate and demonstrate the results widely among multiple end-users to exploit the benefits for SME partners.

The project has been largely successful in attaining these objectives through the research and technology development conducted across six integrated work packages (WPs 2-7)

3.1.1 A-FOOTPRINT Information System (AFIS)
Key innovations and breakthroughs: The AFIS system provides an innovative solution in cloud computing in orthotic prescribing, design and manufacturing database providing a single source integration of digital datasets for SME stakeholders in the orthotic sector and end-user clinicians and technicians.

The AFIS system was successfully built within an Oracle database platform. The design process involved SME partners and other stakeholders to capture relevant input/output data, user interface features, access and storage. The Beta version of the system was hosted in a cloud platform and tested and evaluated by SME partners. It contains the functionality to upload, process, and share data relating to the patient and their dossiers containing clinical/medical data, questionnaire, measurements, diagnosis, treatments, orthotic design and evaluation. The AFIS system is the first component of the integrated A-FOOTPRINT solution with the objective of improving orthotic prescriptions to reduce delays and errors during the design and manufacturing stages, to reduce overall delays and product returns among SME partners. The alpha version product was successfully demonstrated at the pilot factory demonstration event at month 42 of the project.

3.1.2 Computer Aided Design (CAD) software for personalised ankle and foot orthotics

Key innovations and breakthroughs: The CAD software provides, for the first time, a dedicated software design platform directly built to support additive manufacturing and freeform design. It provides significantly new capabilities beyond state-of-the-art to introduce variable wall thickness; new functional design features linked to AM and embedded sensing.

The development of the CAD software was centred on 4 key objectives: OBJ1- To define a co-creation design process for personalised orthoses; OBJ2- To develop a specification for a Personalised Orthoses design CAD/CAM System (POD); OBJ3- To develop a prototype POD system, and test with end users; and OBJ4- To use the defined co-creation process and validated POD system to design a minimum of two new, innovative orthoses. The objective was to significantly improve the fit tolerance of personalised ankle and foot orthoses by moving all orthotic designs from plaster casts, templates and blueprints to digital design solutions; by Integrating co-created digital design, personalised design optimisation and digital manufacturing to provide complete geometrical design freedom; and to deliver a co-created, industry platform ready, Computer-Aided Design software system and 2 prototype orthotic devices verified by reported increase in fit, comfort and aesthetic ratings for prototype orthotic devices in comparison with industry standards among consumers during pilot factory evaluation and field testing.

Co-creation of the new POD CAD system involved two main processes. First, the Consortium SME partners and various end users including orthotic technicians and clinicians were consulted to identify the
partners and various end-users including orthotic technicians and clinicians were consulted to identify the requirements and specifications of the new system. These requirements were collated and distributed for further consultation, refinement and prioritisation. The end-user requirements were logged in a registry and integrated within the software research and development work. The second main co-creation process was based on user feedback associated with release and testing of beta POD software. For each software release, end-users were asked to evaluate the functionality and use of the software. This information was captured using evaluation forms, assimilated and used to inform changes and refinements in next software versions.

The specifications for the POD CAD system were written following wide consultation with SME-based technicians and clinicians. The findings were formally captured and recorded using evaluation forms and then developed within the POD software into innovative features to enable FO and AFO positive correction and orthotic design. The software has been developed to fully utilise the design freedom enabled by additive manufacturing. For example, adjusting the trimlines and thicknesses of AFO’s based on FE analysis. Further designs have been made with the POD system with variable thicknesses, new surface textures, and new functional elements to control motion and redistribute pressure. Novel design concepts which reduce orthotic thickness and weight were also created. Desired and realised specifications also include adaptations on current designs such as colour, texture and retaining media.

The software workflow was developed and implemented on the 3-matic platform from materialise NV. The new features within 3-matic enables the designer to create a custom ankle-foot or foot orthosis in a very short time based on scanned anatomical data directly from the patient or from a scan of a cast. The designer has the means to correct the scanned impression of the leg/foot and to apply new design features on the orthoses which exploit capabilities within layer manufacturing. The steps incorporated within the new software permits:

- Automatic fixing of the scan to remove any irregularities, holes, bad surfaces in the scanned leg/foot/cast to create a better and “cleaner” surface.
- Anatomical landmark indicator in the shape object to realign and reorient ate the scan file so that they are always in a consistent position when the design work begins.
- Positive cast correction which enables the designer to realign the foot and sub-regions in the cardinal planes to pre-specified angles and the anatomically correct neutral position.
- Generate AFO outline where a default outline of the AFO is generated using the landmarks provided. The parameters are automatically generated, although they are still adaptable for the edit.
- Edit AFO outline where the default outline can be edited and fine-tuned by dragging interactive certain regions of the outline. The regions are predefined based on the users input. The outline will always move symmetrically on the medial and lateral side of the leg.
- Generate AFO where the AFO device is generated from the scan. Here the user input are required for the following parameters; Clearance: this is the distance between the AFO and the leg scan; Thickness: the thickness of the orthoses; and the trumpet/ lip parameters are referring to the upper border of the AFO. This is the area which needs some flexibility due to muscle contraction and movements of knee (from stand to sit or the other way around)
- Finish design that include: Create strap slots- to ease attachment of the Velcro straps holes can be as strap slots that keeps the AFO in place on the patient; Local smoothing- to reduce sharp edges and borders by smoothing the AFO; and local morphing- to locally select a region of interest which you then can move in the desired direction.
Same or similar steps are undertaken with the Foot Orthotic (FO) module within the POD system. The specifications for the user interface were an important aspect to the POD CAD development particularly since the 3-Matic engine has been previously described as overly technical. The new interface developments were positively received by end-users during field testing and following major dissemination and demonstration events.

The POD CAD system was used to successfully produce a repository of novel orthotic designs beyond the description of work of two prototypes, and these included both ankle-foot and foot orthoses. Novel design concept for foot orthoses include, for example, pressure relief textured surface, hinged 1st ray, pressure relief via MADYMO optimisation, adjustable rearfoot post, spring arch, and embedded temperature sensor.

Novel design concept for AFO’s include, for example, Articulated hinged AFO, FE optimised AFO, Accelerometer AFO, and SELS AFO.

3.1.3 Design optimisation software routines for personalised ankle and foot orthotics

Key innovations and breakthroughs: Major innovations were delivered in the form of the most advanced biomechanical simulation models of the foot and ankle produced within the AnyBody Modelling system. This model provides an unparalleled level of anatomical detail with new capabilities for scaling via external body scans and input drivers via low-cost plantar pressure (negating the use and cost of expensive 3D gait laboratory data).

This objective was achieved by developing personalised anatomical and functional models of the ankle/foot region in 15 healthy adults and 10 patients with common disabling conditions, utilising 3D medical scanning (magnetic resonance imaging and computed tomography) and gait analysis techniques; employing that data to develop optimisation routines in 2 biomechanical modelling platforms (AnyBody and MADYMO).

Personalised anatomical and biomechanical digital datasets comprising anonymised, 3D gait analysis data and deep anatomy data from MRI/CT imaging for 15 healthy adults and 10 patients with musculoskeletal foot disease was successfully gathered. Simultaneously, researchers at the two clinical centres (GCU and MAS) developed a standardised biomechanical data collection protocol. This was undertaken in cooperation with modelling researchers from WP3 and WP4 and SME technology companies to ensure high-quality data capture, data integration, data output structures and data transfer between work packages.

Clinical centres in Glasgow UK and Maastricht, Netherlands obtained ethical approval for the protocol involving CT imaging exposure. A CT/MRI imaging protocol included a framework for imaging parameters for each modality, and the development, design and commissioning of a novel foot loading rig to be used during CT scans. This rig successfully imposed partial-weightbearing loads to the foot under different poses to enable average and extreme foot motions to be captured.

3D surface scanning was incorporated within the final biomechanical protocol applied in 25 subjects including normal healthy adults and a range of patients with common foot and ankle impairments including flat foot, metatarsalgia and drop-foot associated with stroke. These subjects were recruited as normal and patient volunteers and provided informed consent. Work was undertaken in strict accordance to the ethical framework defined in Annex I and local conditions following site-specific ethical approval. Data was
framework defined in Annex I and local conditions following site-specific ethical approval. Data was anonymised and transferred to partners and successfully input to the AnyBody and MADYMO Modelling system.

From these datasets a normal foot model was developed within the AnyBody software platform. The foot is a complex structure formed by 26 individual bones linked together by a dense net of ligaments and muscles. Therefore the first stage of work involved the definition of the segments of the foot and to give each segment a mass and an inertia matrix. Worked progressed to define the kinematic links between the bones in the foot in two stages. Firstly the basic kinematic constraints with conventional joints of the type revolute and spherical were modelled. From that the centre of rotation and orientation axes were estimated and then improved via optimisation using the motion capture data provided each subject/patient. These conventional joints are not sufficient enough to describe the complex foot kinematic constraints. A further step was taken to complete the model by adding a number of more advanced kinematic constraints such as ellipsoid to ellipsoid contact and kinematic rhythms. This meant that the previous 46 degree-of-freedom model could be controlled with only 20 input parameters. These rhythms were established for toe flexion, inter-tarsal contact, metatarsal head contact, the metatarsal transverse arch, the tarsal transverse arch, and the longitudinal medial and lateral arches. The function of these structures is of paramount interest to clinician and technicians involved in the design and manufacture of personalised orthoses.

The AnyScript foot model was built into the Anybody Managed Model Repository as a novel building block for the human body segments. It represents significant progress beyond current state-of-the-art where previously the foot is modelled a single, stiff structure. Individual patient data was used to drive human walking. By using a new over-determinate kinematic solver of the AnyBody Modelling System, realistic patient specific model reproducing the patient motion was achieved. Further refinement to the foot model took place. Here, CT scan data from healthy subject #1 was matched to the existing geometry of the model via a morphing-based scaling. All nodes were scaled and the joint centres and orientation adjusted. Toes flexion rhythms were also refined as well as the medial and lateral arches using a linear combination joint angles instead of bone heights. Further refinements have been made to convert the cuneonavicular and first and fifth tarsometatarsal joints from spherical to universal joints. With these modifications the joint motions were externally validated against in-vivo measurement data from Lundgren et al 2008 and showed good correlation.

Muscles and ligaments were added to the model comprising 12 intrinsic muscles of the foot; the origin/insertion points based on Yamaguchi et al 2007 were importantly modified to form multiple insertion points, insertion of tendon-to-tendon and blending, such as occur with extensor digitorum brevis and longus to form the extensor expansion.

The major foot ligaments were successfully implemented in the model including the medial deltoid and lateral collateral ligaments, the deep metatarsal transverse, the plantar fascia, the long plantar, the calcaneocuboid plantar, the calcaneonavicular plantar and the phalangeal ligaments. The tarsal region posed a problem since it has no major intrinsic muscle-to-bone attachments in the region providing insufficient muscles to balance all the degree of freedom. Force Dependent Kinematics was used to calculate the tarsal region motion according to the stiffness of the ligaments present but this was found to be too computationally demanding. For now, artificial muscles were implemented in the model corresponding to the dense network of small ligaments.
The next stage successfully developed the use of plantar pressure measurement to drive a foot model in the AnyBody Modelling System. Pressure datasets for the 4 healthy adults and 2 subjects have been collected and used in preliminary simulations within the AnyBody Modelling System with excellent results. A Python script was implemented and is used via the AMS external call function. It creates the appropriate dynamic ground reaction force for the foot model according to the plantar pressure measurement.

From the motion capture recorded data, a set of parameterized drivers has been extracted that can run the foot model with only anthropometric and plantar pressure data as input. It includes drivers that pull the bones to the floor when there is pressure underneath. Interpolation drivers with a base curve from MOCAP recorded motion that can be scaled according to parameter such as neutral arch height or maximum pressure in a certain area. The validation work has successfully modelled joint rotations and muscles actions against published data as criterion validity. Results to date indicate that muscle activation compared to the recorded EMG from our healthy subjects gives good correlation. EMG data has been recorded during the gait trials of every subject in the project. For validating the model the recorded EMG is compared to the predicted muscle activation. Model predictions were improved by implementing a non-uniform time scaling of the baseline drivers.

In developing pathological foot models the transformation of the healthy foot model into pathological model is done by the morphing with landmarks picked directly on STL file representation of the skin surface.

This model represents one of the most comprehensive and detailed models, far beyond current state-of-the-art, notably because it comprises subject-specific anatomical information derived from advanced imaging techniques and comprehensive personalised biomechanical data using kinematics, kinetics and pressure and muscle EMG. The development and delivery of the alpha version of the AnyBody Software Modelling System foot and ankle model showing working kinematics and muscle action. This model can now be driven by subject-specific kinematics derived from 3D gait analysis and EMG muscle signals. Inverse dynamic analysis can now be performed.

A second modelling approach was undertaken in A-FOOTPRINT using multi-body, finite element software package (MADYMO) with the goal to develop a foot model with optimisation techniques to provide patient-specific criteria to enhance the design of a personalised ankle-foot or foot orthoses. A coupling with the ABT model provided an ideal solution because it is scalable and has the muscle forces as outputs that are needed as input for the MADYMO model. Work successfully advanced to create a finite element model of the foot is created to simulate static loading of the plantar tissue. Segmented CT-data of patients and healthy subjects generated earlier was used to derive the geometry of the FE-model. The tibia part of the mesh contains 206 nodes. These nodes are moved down to the plate, pushing the total foot down, enforcing contact between the plantar foot and the plate. As a consequence, the plantar tissue is indented, until the reaction force of the plate is equal to the force measured calculated from the pressure measurement. The indentation is measured and compared to the indentation values measured in the CT data of a loaded foot.

Soft tissue modelling: The soft tissue was initially modelled as an isotropic, incompressible, hyperelastic material, described by a first order Ogden form hyperelastic constitutive model. This model is widely used in the literature to model plantar soft tissue material behaviour, because of its superior non-linear curve.
In the literature it has been shown that nonlinear curve fitting is superior to model plantar soft tissue material behaviour, because of its superior non-linear curve fitting capability. The model in FEBio is Ogden Unconstrained. The material properties used as initial guess were $c_1 = 32.9$ kPa and $m_1 = 6.82$. The bulk modulus was set to $k = 0$. Comparison with pressure data: The reaction force is compared to the experimental force. The desired force is calculated using the insole device PEDAR System. For MAS1, insole X was used. The width of the 4 slices together was 2.7 mm, measured in the CT data. The total length of the area (forefoot and heel) that was in contact with the sole was 155 mm, measured in the CT data the total contact area was thus 418.5 mm. The mean pressure measured on the sensors covered by these slices was 30 kPa. Optimisation loop: Preliminary results show that the use of mechanical properties of the soft tissue from literature does not result in a valid pressure calculation. This has resulted in an optimisation method with improved results.

The beta-version version of the MAYMO model was successfully developed from experimental data on foot anatomy and gait performance. The beta version now is scalable and can be made patient specific, for a range of geometries and material properties. This leads to the possibility of full validation of the model, since the model can be compared with experimental data for both, patients and healthy subjects. For optimisation of the foot orthoses the approach was to focus on topology optimisation to vary local thickness with the therapeutic objective to reduce harmful pressures associated with common impairments such as pain and ulceration. The foot model was coupled with a finite element model of an FO. The FO was computed by an iterative loop, starting by introducing an FE orthoses below the foot: (1) compute the plantar pressure caused by pushing the foot on the insole (2) modify the insole, by making the insole thinner on locations of high pressure (3) repeat the previous steps, until a stable solution is computed.

The optimisation algorithm is written in MATLAB. This algorithm will control the full simulation:
1) Reading of patient specific model parameters,
2) Translation of these parameters into XML to produce a madymo foot and ankle model,
3) The introduction of a predefined insole into the model,
4) Simulation of a predefined motion or pose with both, foot and ankle & insole model,
5) Compare output of the model results with target parameters,
6) Adjust insole geometry by formula, for elements where the pressure is higher than a predefined threshold,
7) Repeat step 4-6 until a stable solution is achieved,
8) Export FE-mesh towards an STL file,
9) Export STL to insole manufacturer.

In terms of optimal AFO design by finite element analysis modelling the following procedure has been applied to determine optimal orthoses for different pathologies. A mechanically optimised AFO device was advanced to Phase II testing in a population of patients who have hemiplegia as a result of a stroke. The design process for these devices combines elements of the modelling results to optimise the design to the individual for manufacturing in SLS.

Deviations
In WP4 there were deviations from the scheduled Description of Work (DoW) due to the withdrawal of partner TNO towards month 12 of the project. The revised DoW set out a revised work schedule including deliverables and milestones and on the whole these were largely achieved. However in task T4.1 the complexity of the model was not achieved to the same level as in WP3 for the AnyBody model; in T4.2 it was possible to scale the model to individual patient specifications but this remains computationally challenging and in T4.3 a numerical shoes and orthoses model was developed but further work required to...
Challenging and in T4.3 a numerical shoes and orthoses model was developed but further work required to advance the complexity and the customisation of both models.

To advance the commercial readiness of this project result it is anticipated that a further 18 months of work would be required, involving the clinical partners MAS and GCU and, importantly, ABT and RSS to ensure data integration and compliance with the AnyBody model and the plantar driven pressure data (for verification purposes also).

3.1.4 Rapid manufacturing techniques for personalised ankle and foot orthotics

Key innovations and breakthroughs: Major breakthroughs were made to benchmark and develop and manufacturing specifications and performance for additive manufacturing of custom ankle-foot and foot orthoses. The work resulted in major innovations in novel orthotic products including embedded sensing. This culminated in the successful demonstration of a SME-based pilot additive manufacturing centre with high level commercial readiness products verified through a number of mechanical and clinical trials.

The first objective was to develop performance specifications for ankle and foot orthosis manufacturing facilities, taking into account orthosis type and intended market sector. Work progressed to create the manufacturing facility specification. The product design specifications coupled with the individual modes of operation depicted for the different SME partners made it possible to define a global set of requirements that a new manufacturing facility should be able to fulfil. Such requirements can be split into: (1) Product size and geometry; (2) Material properties and productivity; and (3) Costing. It was considered that a new manufacturing facility would bring orthotic development one step forward, from the use of digital scan data as input information for the design process, until the capacity to provide variable properties within the same part. This represents an advance in the state of the art related to closed-system based CNC alternatives. In order to represent a technically feasible and cost effective alternative for orthotics fabrication the facility must perform according to key requirements. The final part of the specification established quality assurance measures split into a) on-site and b) laboratory testing. In-house quality assurance measures were established for accuracy and surface finish and hardness tests.

The second major objective was to describe and benchmark of orthotic manufacturing methods in emerging rapid manufacturing technologies to be adopted along the project. The task was conducted in two phases. Phase I focused on the description and benchmark of current and emergent technologies. Phase II examined the scope for hybrid or combined solutions where synergies between different processes are detected. As a recent increase in activity for the development of low-cost RM solutions has taken place, it was important for A-FOOTPRINT to also embrace these developments and integrate them into the development chain, so that it remains on the edge of digital technologies implementation. After observing and reviewing the SME partners manufacturing facilities and processes the benchmark was established for typical processes for AFO and foot orthotic manufacture, productivity, lead times and cost. This included hand-fabrication and state-of-the-art CNC milling. In Phase II rapid manufacturing alternatives were evaluated. This focused on central manufacturing facility based approaches including stereolithography, selective laser sintering, fused deposition modelling, and 3D printing. Desktop type manufacturing equipment was also evaluated and compared including Vflash (3D systems), Object Alaris, and Dimension uPrint Plus.

Although a virtual winner is Selective Laser Sintering there are additional factors to be considered before selecting an alternative such as range of materials and availability, equipment cost, economic performance (economic batch, productivity, etc). According to the overall product requirements there are a number of material properties of interest such as strength, stiffness, hardness and fatigue to be observed for the winning alternative. The benchmark comparison between RM technologies is relatively...
for the winning alternative. The benchmark comparison between RM technologies is relatively straightforward, as critical criteria such as maximum product size and expected productivity rule out 4 out of 7 alternatives. Additionally, surface finish requirements and expected material properties narrow the search to a couple of alternatives (FDM and SLS) which can be differentiated by strategic criteria such as machine price, installation requirements and cost, materials and expected product cost. The sPro-SD SLS Center (3D systems) was selected as the selective laser sintering technology and the equipment installed and fully commissioned at PCK as a pilot demonstration facility. Performance metrics of existing methods against those of the selective laser sintering process were based on productivity and cost, complemented by further research on two other metrics: quality and flexibility.

Productivity levels were found to vary across the SMEs according to market size, company strategy etc. For foot orthoses the productivity benchmark was considered to be between 50-60 pairs of devices per day with cost ranging from €50 to €100. For AFO’s the size of the product and the need for assembly of functional add-ons means that the level of automation is highly limited and as such the productivity benchmark is guiding by thermoforming process as the standard manufacturing route.

Productivity evaluation for foot orthoses firstly considered CAD-CAM fabrication systems with NC milling solutions. Conventional milling systems had moderate cost are capability to provide 1200-1500 pairs per month, however the “productivity window” obtained from SME partners gave a desired target output of 50 pairs of orthoses per working day. Build-time estimates were achieved by benchmarking on generic orthotic design between a number of NC routers using Deskproto software and a library of NC milling alternatives. Build time varied between 13 and 44 minutes. Higher capacity centralised facility based CNC routers were evaluated by undertaking a simulation run using a six-insole 3D file and two high-capacity NC routers. Build time for both machines were similar and superior to single-pair limited machines. NC routing is limited by programming and machining issues which make it difficult to obtain non-uniform thickness shells and complex design with personalised functional elements.

Rapid manufacturing of customised parts offers a number of advantages namely: high flexibility for design changes, geometric freedom, ease for achieving complex features, between others, however when RM is intended for dedicated fabrication, some features have remained unexplored such as: cost efficiency, lead time and overall product quality. Work here commenced with a productivity evaluation for foot orthotic fabrication. Build time estimation sets were performed with a generic orthotic design produced by GCU and indicated a tendency for lower manufacturing times when overall build volume is shared by more than one single component. Sensitivity analysis revealed that optimisation routines for SLS whereby the overall Z height was reduced by nesting the orthotic design in a packed-optimised manner can achieve significantly reduced build times.

Productivity evaluation for ankle-foot orthotic fabrication included build-time estimation for different number of parts. A generic 3D AFO design has been placed in two SLS machines and a second stage of optimization has been performed by minimizing the Z height and packing multiple components in a single build. Results showed that augmenting the packing ratio and minimizing the overall height has a positive effect on the final build time. From the perspective of a fully dedicated manufacturing facility there are a number of strategies to follow in order to optimize building speeds and productivity: Using night-time shifts; optimizing material recycling; fine tuning scan and thermal parameters for higher speed; and advanced nesting of parts thus minimizing unused build space.

Within the reporting period the cost aspect for FO and AFO devices was also modelled. The work
Within the reporting period the cost aspect for FO and AFO devices was also modelled. The work commenced by defining the main cost drivers for rapid manufacturing namely material costs, labour costs, and overhead costs. Sample spreadsheets based on ankle-foot and foot orthotic manufacturing using build times established earlier have been produced. This will allow the SME partners to allocate different cost factors for rapid manufacturing in the final part cost. Break-even curves were then developed to show the cost evolution of the selective laser sintering alternative when build time is optimised for multiple components.

The task proceeded to introduce the techniques employed for the final modelling and evaluation of the productivity of orthotic manufacturing systems. The use of discrete event simulation has been proposed with the initial modelling of the original NC-milling process for functional foot orthotics. The capabilities to introduce slight variations to the systems have been demonstrated by integrating two separate steps that interact closely: scanning stage and manufacturing stage. An additive manufacturing scheme to replace a NC-router with a SLS machine has been also modelled based on three different time estimates as obtained from the sPro SLS software. Results suggest the use of the SLS process must not be scheduled on a daily basis but on a weekly basis with a special emphasis on weekend builds to take advantage of the un-supervised operation cycles.

It is concluded that the use of various “complementing” modelling techniques will be appropriate to show SME partners the best alternatives to increase productivity with their actual systems, in conjunction with various additive manufacturing methods. Further work was undertaken to benchmark conventional and RM methods and illustrated the behaviour of actual systems and the variables that intervene during operation. On the other hand the use of RM methods introduced the possibility to adopt equipment that does not require attended operation for long periods.

A number of low cost RM alternatives based on the FDM commercial process have emerged over time. The productivity in hours per pair is made up of (i) geometry capture time, (ii) orthoses design and (iii) orthoses fabrication time. For the FDM technique, using Dimension SST 768 and uPrint systems have given the total estimated design and fabrication lead-time of 14 hours and 10 minutes for one pair of orthoses. In 3DP technique, using V-Flash system gave the total estimated design and fabrication lead-time of 20 hours and 10 minutes for one pair of orthoses. In Polyjet technique, using Connex 500 system gave the total estimated design and fabrication lead-time of 30 hours and 50 minutes for 5 pairs of orthoses giving the productivity of 6 hours and 10 minutes of time per pair. The total estimated cost per pair is made up of (i) foot assessment cost, (ii) foot geometry capture, (iii) orthoses design and (iv) orthoses fabrication.

Further research successfully compared of rapid manufacturing based systems with conventional resources based systems. Selective laser sintering techniques based system gives minimum total estimated cost of £135.01 per pair with delivery lead-time of 3 days. This gives the advantage to SLS technique based design and fabrication system among all the other RM based design and fabrication systems. However the total estimated cost per pair in conventional resources based design and fabrication system is lower than the SLS based RM design and fabrication system, so its implementation should be justified by alternative benefits not provided by conventional methods.

The SLS based design and fabrication system has a significant advantage over the conventional design fabrication systems which is the fabrication of complex geometrical design features. The other advantage
fabrication systems which is the fabrication of complex geometrical design features. The other advantage in RM based system is removal of manual finishing of fabricated orthoses after the fabrication through milling process. The total per pair cost of £135.01 per pair in SLS based fabrication system can be reduced by reuse of un-sintered material in the build bed. According to Duraform material guide by 3D systems un-sintered material can be used not exceeding 67 percent with the ratio of total material (Guide to Duraform materials, 3D Systems, Inc., USA, 2002).

The reuse of 60% of un-sintered material with 40% virgin powder reduces the material cost from £54 per pair to £21.60 per pair. This gives an estimated total cost of £102.61 per pair, which is a competitive cost with conventional resources based systems with better and improved quality orthoses by SLS based rapid manufacturing system for production of custom foot orthoses.

Comparison of CNC milling vs. Rapid Manufacturing-based production: Based on the previous analysis it is possible to expose the most significant information to discuss the effects of adopting a given technology. The productivity benchmark graph illustrates the relationship between capital investment and the daily productivity that can be obtained. It is clear that the investment on SLS technologies is not competitive in terms of daily productivity, mainly due to RM not being designed as a high capacity production means. However in terms of leadtime, when the factory production is designed in order to take advantage of the unattended production capabilities of RM, by using nighttime production, liberating labour and weekend builds, then it is possible to achieve shorter leadtimes.

Hybrid production systems: An alternative is to merge the existing processes into a single system that exploits the capabilities of both production types: high productivity rates of conventional methods and unattended- longstanding production capabilities of additive manufacturing. The arrangement of a conventional orthotic manufacturing system with two single capacity NC routers, three Rapman machines and a SLS centre with a manufacturing plan of 32 pairs and a processing cycle of 10 hrs was compared. The average daily production of this sample system is 76 pairs, which is superior to both typologies when evaluated individually. As for the previous simulations the actual processing times must be coupled with labour availability, queues, and possible bottlenecks coupled with the restrictions of post mail that consumes at least 48hrs when sending the physical orthotics to the customer. When modelled over a 3 month period it is possible to sample some delivery times that reveal an approximate of 7 days lead-time. Such numbers correspond to a hybrid type-factory with high production capabilities. Similar analysis can be applied to any other combination of processes and technologies along with the processing, delivery times and time in-process.

As depicted in the various scenarios, well established commercial methods are highly productive and not prone to be replaced by their additive counterparts, as long as the RM solutions are limited to small batches and highly complex parts. On the other hand low cost systems such as the Rapman and other FDM-based, appear to be an interesting solution for unattended operation, besides a low cost of operation and capital investment. These systems in particular exhibit high potential for the future as long as some productivity issues, mainly related to speed and finishing are overcome.

It was concluded that the embracement of Rapid Manufacturing methods will be highly dependent on process planning and on the actual design of the orthotics. If complex geometries and highly variable products are to be produced it will make sense to justify the use of additive methods, however in the short term these technologies are more likely to be introduced as “hybrid” solutions that provide “extra
Advances in embedding sensing with ankle-foot and foot orthoses were made in A-FOOTPRINT. Pilot test of selected embedded sensing included: Temperature measurement and data logging using the iButton and Movement monitoring employing accelerometer, gyroscope, FSR & SELS. Using the iButton for temperature monitoring and data logging which indicated whilst feasible direct skin contact is necessary for accurate measurement. However physical placement of the sensor can be achieved using a socket design in the region of interest in the orthosis design.

The use of SELS sensor was investigated since they may provide clinically useful measurements of compliance and quality of activity over time. Preliminary tests were conducted with an AFO to test deflection and bending angle. For walking and stair climbing/descending, the SELS sensor signal showed an activity related pattern with repeatable and accurate output. The integration of sensing information extracted from 3-axial accelerometers, FSR and pressure data shows potential for determining useful gait information with relatively low cost equipment. The challenge remains the electronics integration of such devices and the signal transmission without interfering with the user or adding undesired extra weight.

The rapid manufacturing based research culminated in the development, validation and evaluation of a dedicated orthotic manufacturing cell within an SME production environment. Since this pilot facility is the first one of its kind, to be devoted to full orthotic manufacturing, there is not prior reference for comparing its performance. Benchmark-based performance was based on two different performance factors: materials-related and cost-related. The former one is a narrative of the material options being adopted since the beginning of operations; the latter one described a comparative benchmark based on the Return of Investment Analysis (ROI) across orthotic manufacturing technologies. For A-FOOTPRINT a “centralized” facility based on the Selective Laser Sintering system was installed at Peacocks Medical Group, UK. The pilot manufacturing facility is comprised of all the elements necessary to manufacture orthotics digitally, from the initial 3D captured of the patient’s foot/leg anatomy, to the manufacture and post processing of the final orthotics.

Materials-based performance: The centralized production facility tested different materials in order to establish the most cost-effective formulation to meet the price range and productivity metrics. For each powder type a number of specimens were manufactured and tested and tensile strength and flexural strength values for the previously mentioned materials along the 3 main orientations derived.

Cost-based performance: The economic feasibility of producing customized orthotics is one of the keys for the A-FOOTPRINT project, therefore as part of the performance indicators the elements of cost are being tracked and their effect on to the final cost assessed. A ROI analysis of the SLS-based factory when compared to alternative manufacturing processes was established.

The Return of Investment is calculated as shown in Eq. 1 for each monthly period. The analysis performed corresponds to the simple ROI, i.e. the change in money value over time has been neglected.

\[
\text{Simple ROI} = \frac{\text{Gains} - \text{Investment Cost}}{\text{Investment Costs}} \quad (\text{Eq.1})
\]

Results showed that after month 12 the ROI percentages are: 97.293% vacuum forming, 137.16% NC milling, -41.21% SLS and -2.25% BfB printer. The cumulative cash flow curves indicated that the break-even period for vacuum forming is 1.96 months, 2.64 for NC milling, 32.93 months for SLS and 12.74 months for a BfB based process.
Strategies for improving ROI results: Making optimal use of the build vat can significantly reduce processing times and increase productivity. When adopting a 32 pair/build volume build-strategy, the adjustment in productivity leads to a break-even point of 21.47 months, which means a 34.8% reduction in the payback period for the SLS process. The ROI at month 12 is increased from -41.21% to -29.7%.

In conclusion it was shown that RM is still behind conventional manufacturing in terms of the return of investment, mainly due to minor capital investment required for conventional manufacturing and low cost RM methods. This however, can be overcome by optimizing packing ratios and maximizing equipment use, assuming downtimes and equipment breakdowns are not common. Alternatively, if additively manufactured orthotics demonstrate an improved functionality and can be charged at a premium price when compared to conventional devices, the profitability of using AM for both high-end and low cost systems can be ensured. This is considered the initial step towards the deployment of a generic cost model that is useful for estimating final product costs, split into: material cost (at various usage levels), overheads, direct equipment use and labour.

The final research conducted investigated the pre-clinical performance specifications in terms of mechanical characteristics for prototype foot and ankle orthoses as well as their efficacy in small-scale clinical trials.

Pre-clinical testing employed computational modelling to analyse and optimise device design is the primary tool to achieve these predictions. The results achieved were:

1. Characterisation of materials: The FEA results for the three different axes as taken from the materials dataset showed an acceptable correlation when compared to the experimental PA2200 results and also compared to simple elastic beam theory. It is assumed that a higher number of converging steps would lead to a percentage difference close to 15%.

2. Orthotic device modelling: Using the POD software, AFOs were designed. To validate the FEA approach to personalising the stiffness of the device, two key features were systematically modified in order to produce six devices with a range of mechanical properties. The design features modified were: (1) Trim line location: This feature primarily describes how far the material comes round the shank of the patient; and (2) Wall thickness This variable defines the overall thickness of the device. The effect of wall thickness and trim-line location on AFO mechanical characteristics was assessed through FEA. Maximum deflection and rotation values, compressive and tensile stress values in the ankle region and rotational stiffness were calculated for each model. In terms of rotational stiffness, the most rigid AFO was the thickest one (4 mm thickness) with the trim-line 10 mm behind malleoli while the most flexible one was the AFO with the trim-line 20 mm behind malleoli and 3 mm thickness. In terms of rigidity, numerical simulations indicate that:
   - by positioning the trim-line 5mm posterior (from 10mm to 15mm) while the thickness is kept constant (e.g. 4 mm), AFO stiffness will decrease by 30% which results in increased deflection/rotation from 5,5° (10_4mm) to 7,9° (15_4mm);
   - by decreasing the wall thickness from 4 mm to 3 mm while the trim line is kept constant (e.g. 10mm), AFO stiffness will decrease by 35% which results in increased deflection/rotation from 5,5° (10_4mm) to 8,5° (10_3mm).

AFO deflection together with equivalent stress distribution around the ankle was derived.

3. Patient trials: Successful patient trials were conducted with prototype orthoses in small-scale proof-of-concept trials. Five of the AFOs described above were manufactured in Nylon 12 via SLS. Mode-of-action through alterations to gait parameters in terms of spatial temporal parameters and ankle/foot angles...
through alterations to gait parameters in terms of spatial-temporal parameters and ankle/foot angles during walking was successfully demonstrated primarily around control of ankle motion and moments. These tests were also successfully extended into patient trials conducted in 6 hemiplegic, post-stroke patients comparing standard AFO devices with SLS printed.

Further trials were conducted on SLS printed orthoses, FDM printed orthoses in comparison to SME commercial devices in a head-to-head, mode of action and patient experience trial in patients with rheumatoid arthritis. Here the objective was to investigate the mode-of-action and patient experience of functionally optimised foot orthoses in patients with early rheumatoid arthritis (RA). Two functionally optimised foot orthoses (selective laser sintered [SLS] and fused deposition modelling [FDM]) were tested in fifteen patients with RA < 2 years duration. The novel devices were optimised for three biomechanistic targets exploiting computer-aided design and additive manufacturing. A third standard device was used as the comparator (SFO). Foot and ankle biomechanical effects were compared. Adverse reactions, orthotic fit and comfort, and short-term symptom benefits were also monitored. Results indicated that both FDM (P = 0.028) and SLS (P < 0.0001) orthoses significantly reduced peak rearfoot motion in comparison to shod. The average ankle internal moment was significantly decreased in the SFO (P = 0.010) and approached significance in SLS (P = 0.052) orthoses. SFO, FDM and SLS orthoses significantly increased the peak height of the medial foot arch between 3.6 to 4.4mm (P < 0.001). Peak pressures in the medial (P = 0.018) and lateral forefoot (P = 0.022) regions of interest were significantly reduced for the SLS orthosis. SFO, FDM and SLS orthoses significantly increased midfoot contact area (P < 0.001 all conditions). In comparison to SFO, SLS and FDM orthoses provided equivalent or better patient experience. No adverse reactions were reported. It was concluded that functional optimisation is a feasible approach for orthoses prescription in early RA and has the potential to provide superior mode-of-action responses for biomechanical therapeutic targets compared to standard devices.

Potential Impact:

4.1 socioeconomic and societal impacts

There are two potential major impacts emerging from the A-FOOTPRINT project:

1. 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 morbidity and strong consumer focus on personalised comfort devices to aid health and increase performance in sport and leisure pursuits.
   • The European orthopaedic brace and support market is expected to expand at an annual growth of 4.4% to €446million by 2011 and approximately 70% (€312million) is for reimbursement of ankle-foot and foot orthoses.
   • These profiles present major opportunities for sustained growth which will cover development and production sunken capital and provide for slack to develop second tier strategies for gaining and sustaining competitive advantage.
   • As such, the generic market and the timing of this particular product/service initiative act as sources of competitive advantage. In addition, transparent market strategy and knowledge-based products will enable the SME’s to access increasingly extensive health care and insurance systems which facilitate access and reimbursement.
   • The project cautiously targets:
     o Capturing business with increase growth in the European market within 3-5 years of project completion.
     o Penetrate new and emerging healthcare markets in the personalised orthotic sectors.
     o Move away from third-party contract fabrication to adopt either centralised or distributed manufacturing.
Move away from third-party contract fabrication to adopt either centralised or distributed manufacturing on exploitation of pilot factory trials and business developments.

Penetrate international markets within 3-5 years of project completion, exploiting current marketing strategies.

2. Result in the development of cost-effective personalised ankle and foot orthoses which will have a significant impact on health related quality of life thereby contributing to community societal objectives.
   • In Europe alone it is estimated that 200 million citizens suffer from disabling foot and ankle problems.
   • Foot and ankle problems impact negatively on health related quality of life. They have major cost implications on health systems across Europe and although precise figures are unavailable, the burden is high and growing.
   • A-FOOTPRINT aims to make a significant impact to EU health strategy as the project and its goals map directly to the themes of:
     o ‘Fostering good health in an ageing Europe’ and ‘dynamic health systems and new technologies’
     o The priority areas related to: ‘lifestyle risk- obesity’ in terms of providing effective preventative and rehabilitation interventions.

Contribute to 2008-2013 vision for Medical Technologies in Health by promoting research and market development consideration towards competitiveness and knowledge transfer, and innovation when developing personalised orthotics.

• A-FOOTPRINT is expected to have an important impact at the health level of the EU citizen. The overall process will be adapted to provide devices for most foot and ankle diseases across childhood and adults. Cautious estimates for realistic and achievable targets are:
   • 15% reduction in foot related impairment and disability across a range of musculoskeletal and other foot conditions.
   • Rapid care within 48 hours (thus surpassing the upper limit of 15 days in the call outline).
   • 25% reduction in recovery time based on the improved design characteristics for fit and function as well as novel developments such as embedded sensors for activity monitoring and biofeedback.
   • 15% reduction in societal costs based on cost-effectiveness treatment solution, improved recovery times, faster remobilisation and quicker return to work.

Case study:

• Patients with diabetes and peripheral neuropathy are vulnerable to foot injury leading to ulceration and amputation. This is associated with poor quality of life and a substantial economic burden both for society and health insurance.
  
  Annual costs from the societal perspective increase about 50-fold from the lowest severity stage (€431) to patients with lower extremity amputation (€21,476).
  
  Medical devices (including foot orthotics) constitute the most expensive direct medical care costs for these patients rising from €43 per annum for those with the lowest stage severity to €4488 for those with lower extremity amputation.
  
  The target within A-FOOTPRINT would be to develop a customised foot orthoses for these patients with health and cost gains achieved by devices that had improved accuracy, greater fit tolerance and functionality and, critically for these patients with acute foot problems, rapid manufacture for same or next day fit.
  
  A target of a 15% reduction in annual medical device costs is realistic for the benefits gained through the novel prototype foot orthoses. This would lead to an annual cost saving of €155 per patient. With estimates of ~15 million European citizens with diabetes related foot problems, the potential societal cost
estimates of ~15 million European citizens with diabetes-related foot problems, the potential societal cost savings with this treatment approach would be €2,325 million per annum. Further cost savings would be gained by reduced indirect costs for hospitalisation, temporary work disability, transport and rehabilitation.

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