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Development process: From Idea to the World's First Bionic Prosthetic Foot

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Abstract
A structured methodology for planning and executing the development of new products reduces the complex undertaking of endless choices and alternatives to an achievable task. The development process reduces development time and improves the outcome.

As an example the development of a new prosthetic foot, where the aim is to be the first to market a prosthetic foot incorporating bionic technology, was performed in a very short timeframe delivering a cost effective solution to the prosthetic market.

By framing the scope of development to a set of design criteria the design project is attainable in a relatively short time. In essence the development process brings focus to the development team and gives an image of the project objectives to company stakeholders. Along with review meetings at strategic milestones, where 'go' or 'no-go' decisions are made, the development process ensures that a promising development project is performed in the desired manner, using the appropriate resources with the proper company attention.

Challenges
Össur hf. is a leading orthopedics company specializing in prosthetic solutions and braces and supports. There are several elements that place a challenge on the design and development of new products at Össur. The major elements are listed in the following:

Innovation
Össur hf. is a fast growing company in the medical device industry, growing by 20-30% a year. Continued growth is an on-going company objective and will be accomplished by various means. One of those means is growing through innovation. To accomplish this Össur spends a large percentage of its revenue on research and development, ensuring a continuous pipeline of new products and product updates. By this means Össur manages the goal that one third of the company's revenue should come from new products.

Function
The function of prosthetic components is ultimately compared to the function of the human body. The development of highly functional prostheses is aimed towards restoring biological function. In addition to the natural function requirements we have practical aspects such as minimizing weight and size as a prosthetic component should fit within the natural human

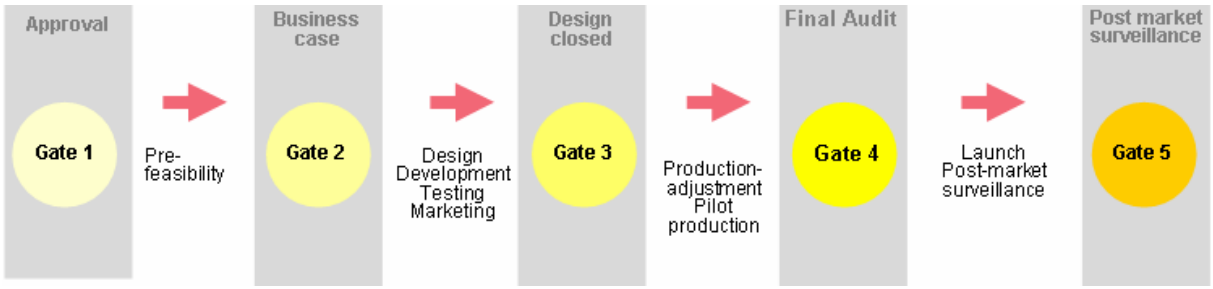
spectrum. The task of optimizing the design with regards to strength but keeping weight and size to a minimum is indeed challenging.

Quality
Since our products are classified as medical devices and as such must adhere to the European Medical Device Directive, additional emphasise is put on safety and quality. Quality and safety are maintained through professional and standardized procedures in product development, highlighting risk reduction and product reliability.

Cost Effectiveness
Governments put an increasing pressure on health authorities to keep costs down. In order to reduce cost Össur strives towards design solutions with affordability in mind, seeking options to lower cost of goods.

Standardized development process

Össur has for several years employed a standardized methodology for planning and executing product development projects. This method is built on the Stage-Gate and consists of five phases and five gates [1]. Each gate is a review milestone where the project group and gate keepers review presented information and give a ‘go’ or ‘no-go’ decision to go on to the next phase.



Picture 1. Product Development Process

The development process ensures the project team’s focus on the goal of the project according to the initial design criteria. The employment of this process has proven very effective to ensure a high product success rate, to reduce development time and to improve the outcome.

The development of a new product begins with a formal approval and a project manager is appointed. The project manager forms a group consisiting at a minimum of the project manager, product manager and the technical lead for the respective product line. During the pre-feasibility phase the business case is formed. Design criteria are developed in relation to the market requirements and fit within the corporate objectives. Technical solutions are brainstormed together with possible production methods. The risk is assessed and the extent of testing is evaluated.

At gate 2 the business case is reviewed and, if a ‘go’ is given, further development resources are allocated and the project team is formed. During the design phase (phase 3) the team performs several design and test iterations until a solution is found. Risk assessment is performed which renders a test plan to verify the funationality, safety and reliability of the product. The tests usually include bench tests, standardized mechnaical tests, wear tests and clinical trials (often referred to as alpha and beta testing). At this stage specialists in intellectual property develop a protection strategy. A preliminary marketing plan is formed,

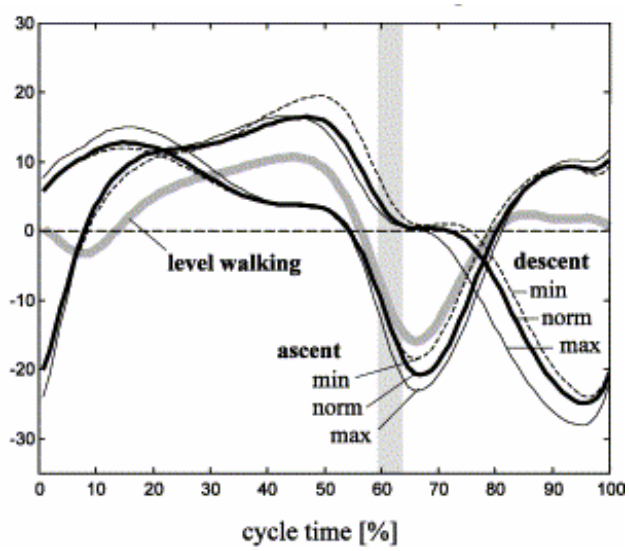
product reimbursement is planned and the trademarks are registered. This phase usually takes the longest time of the development project.
The design is locked or 'frozen' at gate 3 when drawings and specifications are taken to production adjustment. The production method is developed and finalized with a pilot production during which a strict quality plan is defined for the production process. During this phase extensive market preparations are performed and the final sales price is determined with the market and sales subsidiaries. In the case of complex products the sales channel is trained on the features, benefits and sales tactics.
When the development and market preparations are finalized the project team and the product is ready for final audit (gate 4) and subsequent product launch.

The development of the PROPRIO FOOT™

The PROPRIO FOOT is the first microprocessor controlled prosthetic foot incorporating bionic technology by Össur. This product is launched in the middle of the year 2006.

The current state of the art prosthetic feet are predominantly carbon composite feet consisting of forefoot and heel blades. These feet exhibit a range of ankle motion as body weight is applied to the composite blades, a so called weight induced ankle motion. The drawback of purely mechanical feet is that there is no active ankle motion. It became the goal of this project to increase the functionality of prosthetic feet by introducing active ankle motion to simulate the natural function of the human foot. This type of innovation had the potential of becoming the world's first to market and hence there was, from the start, a high emphasis on short development time.

Although the human ankle moves essentially about two axes, the most significant movement is in the sagittal plane i.e. the up and down motion of the forefoot [3].



Graph 1. Natural range of ankle motion during level walking, stair ascent and descent [3]

With a goal to be the first to market, it was of essence to manage the complexity of the design and control the number of hurdles. The design goal was narrowed to a single axis of rotation and to build on the Flex-Foot® carbon composite platform. The functional design was an ankle and foot mechanism that would align itself to variable terrain such as slopes and stairs. This alignment is performed in the swing phase of the gait cycle in preparation to the next stance phase; in addition to that the foot performs a toe movement during swing phase to

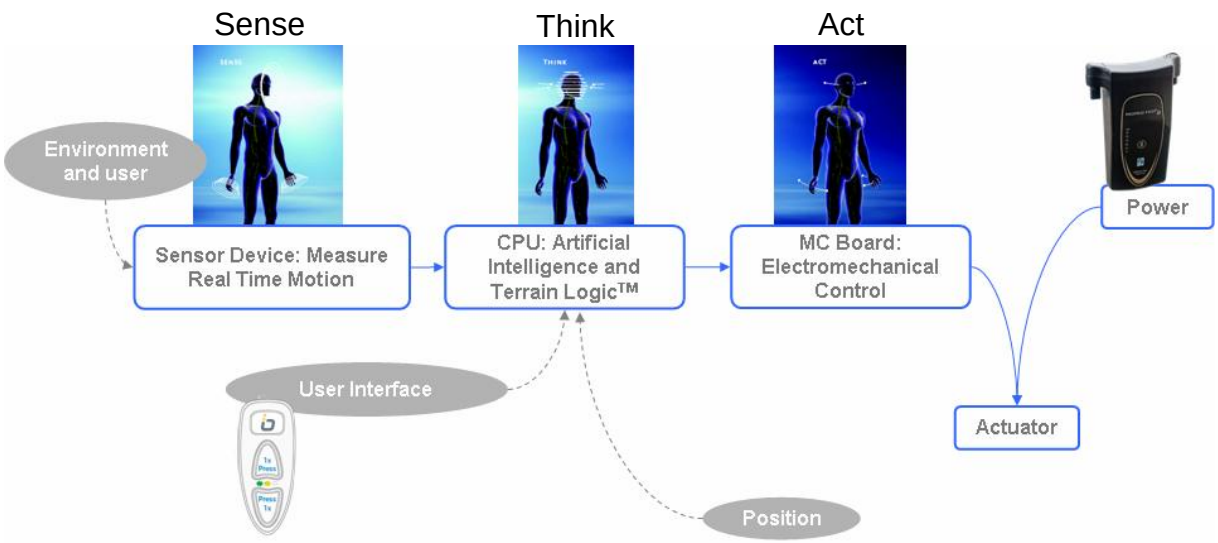
reduce the risk of stubbing the toe into the ground. By limiting the ankle motion to the swing phase, when load on the foot is at a minimum, the motor torque requirements are manageable and possible to select a light and small motor.

Design criteria

After careful deliberation the design criteria are materialized in a document divided into several sections, such as function, performance criteria, adaptability, safety, environment criteria, sales price, minimum product margin etc. The design criteria are a working document during the development process while each section is filled out depending on the project's maturity. Initially user requirements and design input is presented at gate 1 and gate 2 of the development process. When reaching gate 3 the design is completed and verification thereof is entered by reference to test results, reports or other proof of compliance. Finally it is determined if each design criterion is fulfilled with a Yes or No. The design criteria are reviewed frequently during the development and no less than at each gate meeting. It ensures that the development team keeps focus on the goal and realigns their development thereto if any deviation has occurred. It is nevertheless possible to alter the design criteria given new information, but that is done formally with acceptance of the review group.

Technical solution

Fruitful brainstorming and subsequent testing of selected technical solutions rendered a single technical platform for further development. The technical solution, a modular approach, consists of accelerosensor technology, artificial intelligence, a so called Terrain Logic™, and a linear actuator. See picture 2 for an overview of the product's high level system architecture.

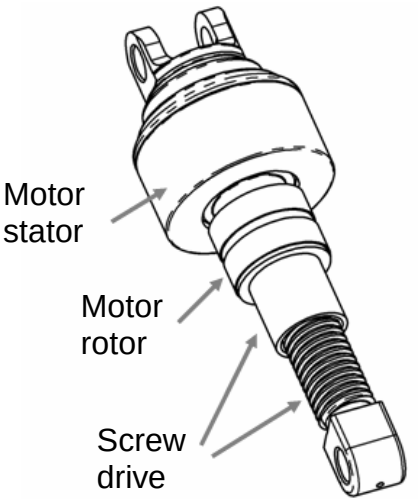


Picture 2. High Level Technical Architecture of a microprocessor controlled prosthetic foot

Combined with the carbon composite foot module and high grade, high precision machined components the technical solution is complete.

The sensor device is located in the ankle unit and measures motion in the sagittal plane. It uses accelerometer technology licensed by Dynasteam Innovation Inc. and samples the acceleration of the ankle at a rate of over 1000Hz. Gait pattern algorithms detect and identify gait events and terrain characteristics by constructing the prosthetic foot's path from the accelerometer information.

The Artificial Intelligence and Terrain Logic™ receive the sensor input and command a correct type of response to the electromechanical control board and actuator. The actuator is a combination of a stepper motor and a screw drive delivering linear motion as the motor turns. Great deal of development effort was needed to ensure minimum friction, optimimum locking effect, low vibration and play, and a quiet but high performance movement. A clever design and the aesthetic appeal of a product is often what separates between a success and a failure [2]. In the development of this product we had to maintain consistency with the appearance of a new technology platform; Bionic technology by Össur. The look and feel of this product was in progress from early stages in the development which ensured a combined aesthetic and technical design.



Picture 3. Linear actuator in a prosthetic foot with bionic technology

Picture 4. PROPRIO FOOT™

Conclusion

The employment and adherence to a standardized methodology as in the development process at Össur ensures a trageted approach in product development. It delivers a final product fulfilling the design requirements in record time, in this case a couple of years from concept birth. It can be estimated that without the targeted approach the development time could have been 30-40% longer. This is a market exposure time that a company that focuses on innovation can not afford to loose. In this case the goal, to be the first to market a microprocessor controlled prosthetic foot, was reached with the aid of the development process.

References

[1] Cooper, Rachel and Mike Press. 1995. “The Design Agenda: A Guide to Successful Design Management”, John Wiley and Sons. Chichester.

[2] Peters, Tom. 2005. Design. DK.

[3] Riener, R., Rabuffetti, M., Frigo, C. 2002. “Stair Ascent and Descent at Different Inclinations”, *Gait and posture*, 15, pp. 32-44.