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Design Framework for Heel Adjustable Prosthetic Ankles: Enhancing Dynamic Foot Versatility in the Context of the Nova Foot by Gyromotics

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This paper suggests a modular design framework for integrating a TRL3 manually adjustable ankle joint—referred to as *core mechanism*—into the Gyromotics product portfolio. The framework addresses project planning, team composition, product lifecycle, and supply chain considerations, ensuring alignment with regulatory, and user-centred design principles. The proposed mechanism aims to improve pressure distribution, enhance gait adaptability, and expand functionality across a range of user activities and environments.

Prosthetic ankle; product development; portfolio management

1. Introduction

The loss of a lower limb represents a physical, emotional and social challenge, impacting mobility, independence and quality of life [1], [2]. The main causes include peripheral artery diseases, diabetes mellitus, and trauma. Trauma particularly prevalent as the leading cause in low- and middle-income countries and among younger populations [3]. According to [4], lower limb amputations accounted for an incidence of 967,473.56 and prevalence of 23,067,244.56. Of these, individuals aged 0 to 19 years represented 11.2% and 3.9% of the cases, respectively. Nonetheless, only 5-10% of people who could benefit from prosthetic products have access to them [5]. Given the magnitude and impact of limb loss globally, the demand for innovative, cost-effective, and functionally effective prosthetic solutions has become increasingly urgent.

In response to this need, Gyromotics developed a high-performance modular prosthetic foot for users with a mobility level between K2-K4, starting at age four [6]. Its modular architecture allows for customization of appearance, size, and suspension, enabling adaptation to individual user preferences, foot dimensions, and activity levels. Additionally, the design simplifies maintenance, reduces downtime, and minimizes reliance on specialized technicians. The integrated suspension system also provides limited supination and pronation, improving comfort and adaptability during ambulation.

Despite the design benefits and positive user feedback, the foot lacks an ankle joint mechanism, resulting in a fixed, neutral ankle position. This increases socket pressure on the stump, influenced by knee and ankle kinetics [7]. Moreover, the absence of dorsiflexion and plantarflexion adjustability limits the prosthesis's adaptability to different shoe types, terrains, and activity levels.

To overcome these limitations, Gyromotics aims to integrate a manually adjustable ankle joint that enables users to modify the ankle position according to their performance needs and surface conditions, thereby enhancing functionality and ergonomics.

This paper suggests a modular design framework to support the integration of a manually adjustable ankle joint mechanism—referred to as the *core mechanism*—into existing prosthetic foot products, with a particular focus on the Nova foot by Gyromotics. The modular nature of the framework allows for adaptation to various foot designs without compromising functional integrity, facilitating its implementation across different products and companies. This is achieved by standardizing the core mechanism while allowing the interface and bracket components to be customized for product-specific requirements, ensuring full compatibility with t the core system and seamless integration within the company's product portfolio.

2. Methodology

Based on literature and field research within the company, this paper presents a design framework for the implementation of the core mechanism into the portfolio of Gyromotics, focusing on project analysis, product lifecycle, and portfolio management. The research question addressed in this paper is: What design framework can support the integration of a manually adjustable ankle joint into existing prosthetic ankle-foot products?

3. Project analysis

The proposed ankle mechanism is designed to improve pressure distribution, enhance gait adaptability, and expand functionality across a wide range of user activities and environments by enabling ankle adjustment in dorsiflexion and plantarflexion. It is intended for users aged 8 to 70 years, with a maximum body weight of 125 kg, in alignment with the P6 category defined by ISO 22675. To ensure safe and effective use, the core mechanism must remain within its intended application.

3.1. Market strategy

Gyromotics is a company committed to addressing the scarcity and economic burden of prosthetic feet for children, adolescents, and adults by designing a high-performance foot suitable for daily and active use. As mentioned above, the target audience is active (K2-K4) lower limb amputees between 8 to 70 years of age with a maximum weight of 125 kg.

The market strategy is centred on global distribution with initial market entry focused on Europe for strategic and operational reasons aligned with Gyromotics' business plan. Therefore, a patent analysis is crucial to prevent patent infringement in the different countries.

The direct competitors of Gyromotics for the development of the ankle mechanism are Össur, Ottobock, College Park, Endolite, and Freedom Innovations. These companies offer the adult prosthetic feet Runway, Taleo Adjust, Pro-Flex Align, Accent DP/IP, Brio,

Freestyle Swimming, and Freestyle Swimming™ feet capable of adapting to different footwear heel weights with a push button mechanism. However, until November 21, 2024, no prosthetic feet targeted to children had an adjustable ankle mechanism to adapt to different hill heights. Additionally, as of the date of publication of this paper, no competitors offer a heel-adjustable ankle prosthesis capable of enabling angular adjustments in the sagittal plane to support high-demand daily activities such as running. Consequently, the implementation of the proposed core mechanism presents a valuable opportunity to differentiate the company's product offering and enhance its market position.

Furthermore, it is essential that the ankle design aligns with the company's business strategy. According to Gyromotics' business plan, the target manufacturing cost for the ankle mechanism is €300, based on an optimal total production cost of €2,500 for the complete foot. To meet this target, conventional manufacturing methods—such as CNC machining—are preferred, due to their cost-effectiveness in mass production and their broad accessibility within European and non-European countries.

3.2. Team composition

The development and implementation of the prosthetic ankle require a multidisciplinary approach. Accordingly, the recommended team composition for integrating the core mechanism into a prosthetic foot is presented in Table 1. Note that not all team members need to be in-house; roles such as the Certified Prosthetist Orthotist (CPO) and manufacturing engineer may be fulfilled by external partners or collaborators.

Main role	Team members	Members specialization
Project leader	1	Engineer
Sales & Marketing	2	Operations leader, supply chain specialist, quality assurance specialist
Operations & Logistics	2	Operations leader, supply chain specialist, quality assurance specialist
Research & Development	3	Biomedical engineer, design engineer, manufacturing engineer

Table 1.; Team composition

3.3. Tenability

To ensure worldwide access to the prosthetic device, it is important to follow the Standard for Prosthetics and Orthosis. Conversely, to minimize supply chain costs, the product should be optimized for local manufacturing within each production centre. This approach would streamline logistics, reduce shipping expenses, and enable quicker distribution.

4. Product lifecycle

Implementing the core mechanism requires a throughout evaluation of the product lifecycle, given that to implement the core mechanism into the design portfolio it is required to fit its production within the company, and the user interface and the attachment should be designed. Key stages include project planning, R&D, manufacturing, supply chain, testing and validation, regulatory compliance, market preparation and launch, and support and feedback, as indicated in Figure 2. However, most significant changes are anticipated in project planning, R&D, manufacturing and supply chain.

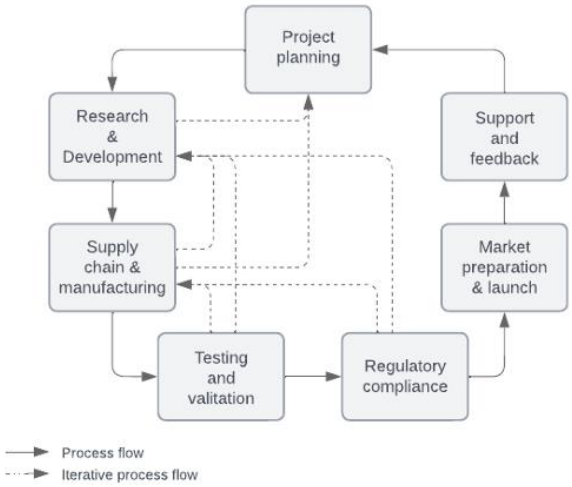

Figure 1.; General representation of the ankle product.

4.1. Project planning

Initially, the project initiator, often the project leader, should gather information regarding the project justification, scope, design criteria and requirements, expectations, timelines, and resources available. The planning document should provide a clear description and timeline that encompasses the project scope, project team, project goals, milestones, project stages, tasks, responsibilities, dependencies (including approval procedures), meetings, resources (software, hardware, people, and budget), and expected type of documentation per task. The planning document should be flexible to changes in tasks but not in milestones deadlines to adhere with the goals and timelines of the company.

Furthermore, all documentation must align with the Medical Device Regulation (MDR) and ISO standards 22675 and 103228, while ensuring knowledge transfer, enabling anyone in the company to replicate the implementation process.

The planning document and documentation files should be incorporated into the company's product lifecycle software to ensure proper communication between team members and the different areas of the company. Moreover, the project leader should guarantee the existence of weekly meetings to monitor the advances and challenges within the project.

Internal and external stakeholders should be involved in the beginning of the conceptualization stage, for key design decisions, and results validation to gather feedback on product performance and quality. Meanwhile, potential users should be involved during the conceptualization, testing, and validation to increase product quality and market success.

4.2. Research & Development

To ensure consistency and effective communication within the R&D departments, members should follow a standardized design methodology, quality standards, and technical documentation. The design methodology should follow an iterative process that includes task planning and clarification, conceptual design, embodiment design, detailed design, and design validation followed by risk management. Additionally, the team must verify that the manufacturing equipment in the production centres is adequate for mass production, desired tolerances and desired material and production quality.

The design approach for developing the attachment system and producing the ankle should comply with ISO standards 22675 and 10328, along with the required technical documentation for medical certifications in each target market, such as the MDR within the European Union. Additionally, the design requirements

outlined in early stages of the project, should be addressed according to the prioritization of the design criteria, ensuring the creation of a feasible and user-centred ankle solution for end users. Conversely, the user-interface, should align with the interface design requirements and usability studies conducted by the company or external parties, enhancing ergonomic accessibility.

The use of CAD-based models, static and dynamic FEM analysis, and additive manufactured prototypes is recommended to validate the interface and attachment design, enabling efficient analysis of load distribution, stress behaviour, and ergonomic performance with potential users, while optimizing both cost and development time. Followed by this analysis, the company should validate the ankle-foot prosthetic with a high-fidelity prototype. The goal is to determine if the functional, performance, interface and additional quality requirements are met.

The intended outcome is a complete ankle system (comprising the core mechanism, foot attachment, and user interface) capable of withstanding a heel and forefoot load of 4852 N during static testing, as well as dynamic loading ranging from 50 to 1521 N at 1 Hz, in accordance with ISO 22675. The system must exhibit no measurable backlash, maintain a total weight below 467 g, and align with the ergonomic accessibility requirements.

Lastly, the team can peruse the CE marking to implement the foot into the market. To achieve this, the technical dossier documentation of ankle should comply with the MDR.

4.3. Supply chain

The implementation of the core mechanism and the development of a new ankle can represent changes in the supply chain. However, the impact relies on the availability of human, economic, and material resources, and weather the ankle is produced and tested in-house or is outsourced, based on the company short- and long-term goals and current business strategy. If the current suppliers and providers can supply the materials and components required to manufacture the ankle, no major changes should be expected. If production is outsourced, the company must build strong relationships with external suppliers and should assess if manufacturers, providers and suppliers meet quality standards, production capacity, lead time, and outsourcing budget.

5. Portfolio management

To optimize financial performance and enhance R&D efficiency, each product should align with the business strategy while remaining flexible to dynamic market conditions. A well-balanced portfolio incorporates both short- and long-term initiatives as well as a mix of high- and low-risk projects for the efficient allocation of limited resources. Such balance allows the company to allocate scarce resources efficiently and ensures that the portfolio aligns with the company's business model [8].

Therefore, for the core mechanism to be integrated into the portfolio, the mechanism, interfaces, and foot attachment must align with the company's image, goals, and objectives, addressing the requirements of active users, leverage innovative solutions, and complement the existing range of products within the company. Additionally, the product should align with the technical and performance requirements stablished by the company, together with the MDR and ISO standards 22675 and 10328.

Furthermore, since the development of a prosthetics should be user-centred, the Standard for Prosthetics and Orthosis should be taken in consideration when developing the business plan and implementing a new product into the portfolio.

6. Conclusion

This study presents a modular framework for the implementation of a manually adjustable ankle mechanism into Gyromotics' existing prosthetic foot product line. By aligning with the company's strategic goals, regulatory requirements, and user needs, the proposed core mechanism enhances the functional adaptability of lower-limb prosthetics. It allows users to manually adjust ankle alignment in the sagittal plane, improving comfort and performance during diverse activities and with varying footwear. Key considerations—including modularity, manufacturing feasibility, standard compliance, and product lifecycle integration—were addressed to ensure a scalable and sustainable solution. Ultimately, this integration has the potential to increase market competitiveness, extend product utility, and significantly improve the quality of life for lower-limb amputees, particularly children and adolescents.

7. References

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