

# **Holly grail of Prosthetic Foot design – Elite Foot**

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## **Background: - History of development**

During the early 1980's the prosthetic industry experienced for the first time the concept of compliance in the lower limb prosthetic design. The Multiflex ankle by Blatchford pioneered using rubber compliance as part of the main structure of the Endolite system. This device remains as one of the most popular ankle/feet devices of the last 2 decades providing natural ground compliance through 6 degrees of freedom, providing rapid stability at heel contact, damping the shock loads, allowing a large range of planter flexion and natural roll over to initiate dorsiflexion to complete a comfortable secure gait cycle. The use of compliant material facilitates adapting to uneven ground by allowing controlled motion in medio lateral direction. In the late 80's Mind+ who was able to successfully use the compliance of polymers in the foot keel to absorb the strain energy during roll over introduced Seattle foot. Combination of this energy storing foot with Multiflex ankle provided a high a degree of compliance for shock absorption, ground compliance and assisting propulsion providing an energy efficient gait for most trans tibial amputees. For trans femoral amputee the combination of this foot and ankle with the use of compliance in the Endolite Stabilising Knee joint through introduction of stance flexion for the first time enabled the amputees to experience high degree of flexibility in the construction of lower limb prosthesis. The over all results were enhanced comfort in absorbing the loads causing shear forces at stump socket interface, ground compliance providing stability on all uneven terrains, controlled knee flexion during mid stance to limit the excessive rise of body centre of gravity and assistance in initiation of swing using stored energy in the keel at correct ankle orientation.

The 1990's were then the revolution of many advance prosthetic foot design utilising the properties of carbon and glass fibre composites and the new understanding of amputees biomechanics and the benefit of compliance and flexibility in the structure of prosthesis. However, with increased activity of the modern amputees, the current devices showed new limitations in enabling the amputee to benefit from the full potential offering of a prosthesis that could enhance their mobility and rehabilitation. Zahedi et al (1994) described a pilot study of comparing 19 different modern prosthetic feet from performance, to fitting, from weight and deflection property to commercial cost and reliability. The conclusion was that none of these commercial feet were adequate for the modern users. The gait analysis data on this study showed the need for enhanced dynamic response foot as described by Harris et al (1995) and further need to dynamically balancing the heel cushioning action with toe's release of strain energy to assist propulsion. This lead to development of the Mercury foot by Blatchford, which for the first time attempts to create a dynamic balance action. Combined with tele torsion pylon device, which provide 13mm of axial spring deflection, this foot in many cases has proved to enhance the comfort at higher activities such as juggling and sporting activities of average modern amputees.

## **The Need: - User requirements**

Despite the success of these advances by Blatchford and many of competitors in this field of development, the new limitations faces the amputees are overall weight of the devices at distal end of the prosthesis, and the need for independent ground compliance to further enhance shock absorption and harvesting of strain energy.

Various biomechanical studies were conducted on modern feet design and analysis of data showed the need for independent control of heel of deflexion during early stance phase, providing an optimum fore shear on ground reaction measurements. 4 active trans tibial amputees and 2 trans femoral amputees were tested using the gait laboratories at King Health Care and Queen Merry Hospital NHS trust in UK. The diagrams 1 and 2 below shows typical ground reaction forces in the form of Vertical and AP shear forces as well as combined butterfly diagrams highlighting short duration of load support during early stance, rapid transfer of load to toe and limited propulsion assistance due to mass inertia created during the walking cycle and/or assistance due o release of strain energy. Additional study was carried out on amputees ability to go around corners and manipulate obstacles by manoeuvring around them Strike et al (2002) showed the impact of inclusion of torque absorber by measurements of kinematics and kinetic parameters of amputees walking around the corners and demonstrated the improvement provided. However, there remains a limitation that most amputees require on average to take 2-3 steps more than normal able bodied subject to take when needing to go around corners.

Diagram 1

Diagram 2

In parallel the amputee survey of existing modern feet users provided a qualitative insight into the overall function, weight, ability on shock absorption and perceived propulsion or energy return. Additional information on ease of alignment, feeling of load transfer, the sensation during standing, stationary position as well cosmetic appearance and overall impression were collected. The diagram 3 below shows typical survey form collected from over 10 active amputees median age of ..... years with eldest .... Years. The results highlighted the issues as perceived by the amputees and through interview conducted with 5 prosthetists on the fitting and selection and matching the prosthesis, additional needs were identified. Diagram 4 below shows the preliminary specification drawn for the new foot.

Diagram 3

Diagram 4

Review of the literature biomechanics research identified prediction based on mathematic and theoretical model of the optimum foot design. Childress et al (2004) highlighted three interesting consideration as the holly grail of the future feet design. Based on detail modelling and verification and analysis of their theoretical model, the outcome were the need for maximising shock absorption, create roll over curvature based on 1/3 of the length of the prosthesis and maximise the propulsion at correct instance of gait cycle.

The above requirements were then reviewed against the market need and commercial affordability under various re imbursement system. Assessment of competition and identification of opportunities from commercial standpoint and various changes in market pressures due to increased restriction in overall funds available provided additional requirements, which was corporate into the list of needs for new prosthetic feet.

Finally with introduction of Medical Device Directive in Europe and requirements of compliance with EN 12523 in managing risk of new medical devices, and re view the ISO10328 and development of a new draft FDIS 22xxx for testing of modern compliant feet system, it is necessary as part of the requirements to identify the

future regulatory needs from safety standards, as well as quality assurance and need for compliance with new good manufacturing practice as required by Federal Drug Administration in US and ISO 13485.

### **Vision: - Innovation**

Following analysis of the needs and detail study of the biomechanical requirements, through a series of ideation and brain storming sessions, several concepts solutions were created. These concepts were reviewed and the ones, which had potential to provide realistic solutions, were drawn. Diagram 5 shows one of the early concepts developed by the co-authors Harris and Smart, which was tested against the marketing requirements specification. The vision as with all the pioneering culture of new product development at Blatchford is set around best use of affordable and proved technology and design, combined with optimum use of advanced materials fused in the core understanding of the science of amputee locomotion. Integration of design and advance manufacturing enables stretching the boundaries of the application of technology within a realistic framework of mass-produced capability of innovative product development.

Diagram 5

Through a selection process a concept was evolved which provided a solution to the main requirements. The diagram 6 shows the principle of the independent spring, the shock absorption of the heel using composite combined with option of rubber dampers to absorb high frequency impulse loads, balanced ground compliance to maximise the deflection of the springs to match the body mass and the loads generated during increase activity, the correct curvature of the toe section to provide optimum role with least energy consumption, the split spring to provide compliance to an even ground and maximising the harvesting of strain energy on each toe spring for energy return and finally the ability to create an asymmetrical shape of the toe which facilitates the ground centre of pressure to naturally progress medially at late stance for smooth and energy efficient load transfer from prosthetic side to the sound side. Diagram 6 shows the principle of operation of the selected concept springs

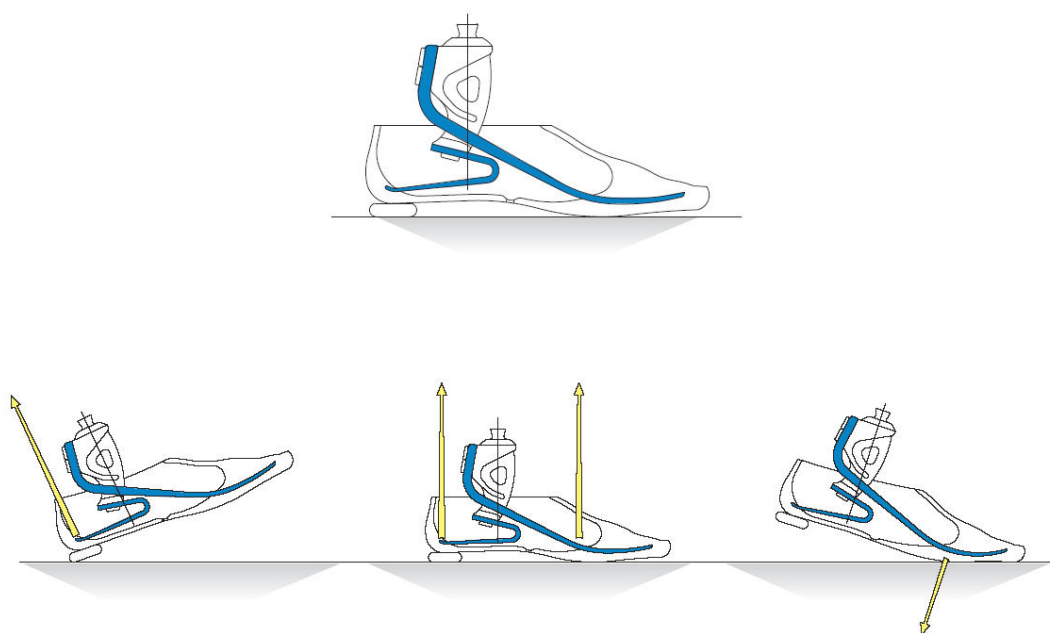


Diagram 6

Diagram 7 shows the model of the early prototype used for clinical experiments by the co-authors Harris and Smart. Once the concept was approved, the product design specification was created identify all the requirements and bench marking on development risk assessment.

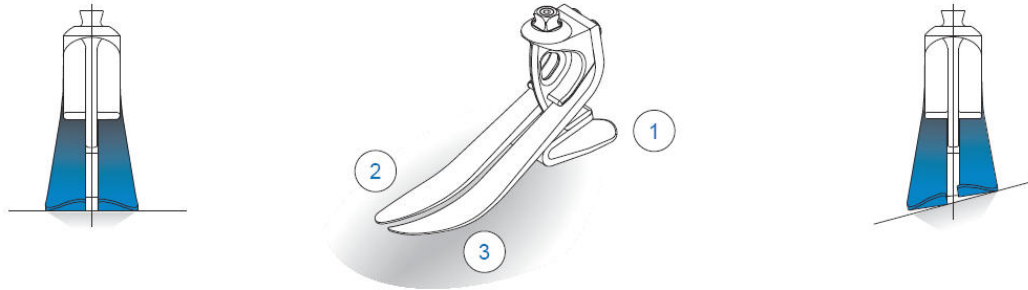


Diagram 7

### **Design Challenges: - Commercial requirements**

The USA market at present has significant need to meet higher expectation with prudent use of their resources. Hence the Medicare L coding system of reimbursement is continuously being reviewed for additional features, which are useful for the amputee mobility and rehabilitation. Similarly in Germany and most European countries, the medical insurance and welfare agencies are continually seeking to obtain the best performing and most cost effective prosthetic products. The Clinical governance is being established in UK NHS rehabilitation services to identify the choices for the prescribers. In view of these market pressures, a major design challenge is to develop what is best for the amputee, following the Blatchford mission of “Patients Comes First”, while meeting today’s commercial requirements.

In addition due to increased competition, and large number of competitive products, there are also many derivatives of the same general foot design idea, which have been able to obtain protection despite the general nature of design. Hence there are additional design challenges to those already identified for meeting the user and commercial requirements and yet avoid pitfalls of maze of intellectual property dominating this field.

Finally due to increased competition, there are increasing market tendencies for trial of new product in search of early satisfaction of the amputee. This has resulted in increase number of new products, which in turn has created pressure on development cycle time and general prosthetic product life in the market. Interestingly one of the latest design challenges is the ability to reduce the development cycle and yet remain flexible to adapt to new alteration and change of objective as the result of introduction of new product by the competition during the development stage. Hence the need to have closer link with market and all the stakeholders so that the design satisfied their changing needs

### **Engineering: - Realisation**

In order to reduce the cycle time, there are areas of concurrency in design and engineering. The evolution of design is through quantification of the major elements such as spring which requires detail lay up of the composite material to provide the correct stiffness to satisfy the structural requirements and at the same time to

facilitate the required shock absorption and population through correct load deflection characteristics. Diagram 8 shows the typical load deflection of toe spring and historieses in the system.

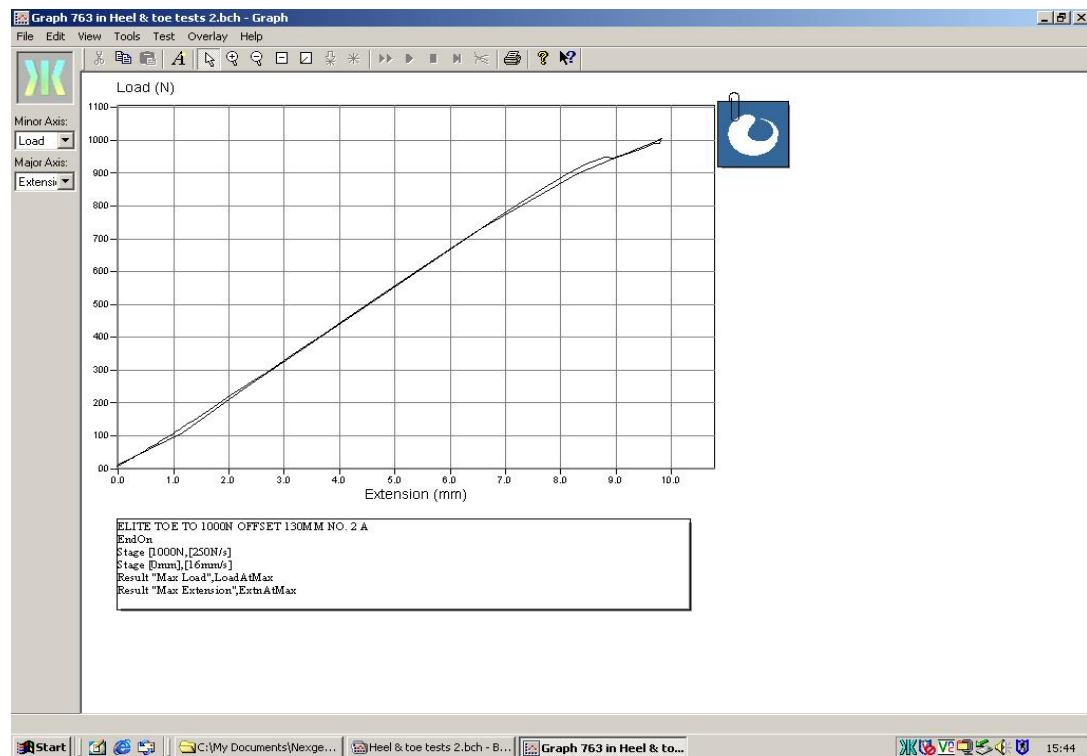


Diagram 8

Increased activity generates higher loads, where the level of strain accommodated in the length, curvature and thickness of the spring will limit the performance of the foot in normal walking. Equally change of cadence and walking at different speed as well as running requires different load deflection characteristics. Balancing these engineering challenges against the structural integrity of the design and safety of amputee undertaking different sporting activity, against maintaining comfort of walking is provided through provision of a range of heel and toe spring. Currently there 9 sets of spring which are evolved through clinical testing, and iterative engineering modification

### Validation and Verification: - Clinical Evidence

In order to continuously provide successful products, it is imperative that users need must be satisfied. In addition all other stakeholders expectation must also be met. However, there is also a need to demonstrate that the original design specification remains valid and met by the prototypes. In addition, the procurement agencies in most countries would like to see the clinical evidence supporting the claims that manufacturer make. In order to meet these, the process of validation in the market by the market at every stage of development from feasibility, through initial prototype, to pre production in undertake. The clinical trial summary below in table 1 shows the location and duration of trails and modification identified as the consequence of the validation. Table 2 shows the matrix created for selection of the different spring to match the weight and activity of amputee based on initial trails.

Table 1

Table 2

This process of validation in the field is also complimented by collection of evidence from kinetic and kinematics measurements clinically validating the aims of the design. Initial gait analysis data revealed the significant difference between the way the trans tibial and trans femoral amputee uses the Elite foot. Diagram 9 shows the foot design names "Elite foot" on typical trans tibial amputee.

Diagram 9

The AP shear forces have provided a useful tool to optimise the alignment of prosthetic foot on trans tibial amputee. This technique is now part of the routine alignment fitting process using gait analysis facilities at King Health Care NHS trust in UK. The results collected on typical Elite foot user are shown in diagram 10.

Diagram 10

Additional data collected shows the combined vertical and horizontal ground reaction forces showing the pattern similar to that of able person. There are clear evidence of the energy return by enabling the vertical component of the load at roll over to go well above (125%) of the body weight. Diagram 11 shows the results.

Diagram 11

The benefits of asymmetrical toe spring were measured using the centre of pressure path and location of ground reaction force vector. In repeated cases, it was noted that at the last instances of the stance phase, the force vector was moved medially when compared with test results from the same amputee, maintaining the same alignment and just changing the toe spring. Diagram 12 shows the medio lateral ground reaction data measured in the gait laboratory of asymmetrical and symmetrical spring on typical trans tibial amputees.

Diagram 12

In addition to validation and collection of clinical data it is important to verify some of engineering assumptions, particularly those that affect the safety and structure of foot. Design Failure Mode Engineering Analysis developed for medical devices are used through out the development stages of Elite foot. The FMEA outcome shows all the high-risk areas, which are either verified by developing specific functional test to insure reliability and robustness, or validated the design by clinical investigation and biomechanical assessment, or through developing means for inspection and measurements to ensure reliability and quality during manufacture. The diagram 13 shows the structural testing of the Elite foot as per ISO10328 foot test for 125 kg amputee.

Diagram 13

### **Implementation: - Production & Selection**

The final stage of development is the implementation into manufacture. The Elite foot covers the range of amputees from foot size 240mm to 300mm. The standard 9 sets

of heel and toe spring cover the weight of 44Kg to 125Kg amputees of low, medium to high activities. For higher weight up to 166Kg the spring can be made to order. The cosmetic foot shells and sliding sock to insert the foot are shown in diagram 14.

#### Diagram 14

The validation through clinical investigation showed that for most trans tibia amputees the heel spring is preferred one level lower than original design. This process of selection and the matrix associated was reviewed and new fitting instruction is produced. In order to facilitate selection of the correct spring, a virtual selection software is developed enabling the prescribers to match the activity and weight more closely from a sliding chart linked to visual estimates of level of shock load and level of absorption required, and level of energy collected and propulsion assistance provided.

Diagram 15 shows the selection simulation from the virtual selection software.

#### **Conclusion: - Future direction**

Despite the longer than anticipated development cycle time, the Elite foot typifies the strength of innovation in meeting to days amputees need. The amputees who have participated in the early trials have mostly provided a very positive feed back and expressed a perception of enhanced comfort. In one case there is a need to control the heel function more closely and in a few early cases, the selection process was a lengthy procedure due to iteration. However these feeds back has been incorporated into change in the final product and the only factor not as yet verified is the long-term repeatability and reliability of the product beyond 2 years of life. The early structural tests complied with was simulated to 3-5 years of life.

Further research in understanding the biomechanics of non straight walking ambulation is required to enhance our understanding and identify the requirements for the next generation of the products to enhance current foot design. The Elite foot due its simplicity of design has opened a new chapter for Blatchford new product development, where utilisation of the science and familiarity with the real needs of amputees enables utilisation of simple solutions to meet increased demands for mobility. This process of development has been evolved to develop new feet for moderate activity amputee and more advance feet with more capability to absorb even greater shock load and store larger strain energy and greater propulsion.

#### **Reference:**

- 1- Zahedi et al 1994 Orthopeadic Tecknik
- 2- Harris et al 1996
- 3- Strike et al 2002
- 4- Childress et al 2004