Development of high performance parasport prosthetic limbs: a proposed framework and case study

Abstract

Sport with a disability has progressed from undertaking physical activity for recreation to one of a high performance environment at competitions such as the Paralympic Games. There is currently limited information and guidance to help inform stakeholders as to how to develop the high performance technology of elite athletes who possess limb absence. In this manuscript, a conceptual framework for high performance prosthetic limb creation is presented. This utilises a synthesis between contemporary product design theory and a review of existing case studies. This proposed framework is then applied to a case study. Ultimately, the framework provides an indicative guide to the creation of prosthetic limbs that emphasise technological performance enhancement over that of mere sporting participation.

Keywords: Prostheses design, amputation, sport

Background

Participating in sport with a disability often requires the use of equipment to either facilitate it or to provide some margin of contribution to an athlete's performance (Bragaru et al. 2012). Evidence of those wishing to perform sport with a physical disability has been apparent since the 19th century (Gold and Gold, 2007). A recent review of the literature has revealed that published research and clinical experience with regards to the creation of sports-specific prostheses is extremely limited (Dyer, 2015a; Santana et al. 2016). Modern sport with a disability is a highly competitive environment (Gold and Gold, 2007) so whereas the motivations to participate in this have evolved, so too should the performance of assistive technology needed to support it. However, in the case studies identified in systematic reviews (Dyer, 2015b; Santana et al. 2016); very few have focused on the needs of elite-level participants. As a result, many stakeholders may not typically possess the specific needs and experience that competitive assistive technology design may require. This would mean that athletes who wished to undertake sporting endeavours would not be supported as well as they could be and the lack of published attention to this end could act as a barrier to those who might otherwise be interested in such pursuits.

Case studies of sports prostheses design suffer from a paucity of attention in this area (Deans et al. 2012) and particularly in Paralympic Games disciplines including cycling (Dyer, 2015b). Instead, most discussion has typically focused on those with limb absence wishing to undertake recreational exercise rather than competition (Couture et al. 2010). A participation-focused approach to prosthetic limb creation has been evident in running (Nolan, 2008) or other sports such as golf, fishing, baseball, cycling (Bragaru et al. 2012) skiing McQuarrie et al. 2015), triathlon (Gailey & Harsch, 2009) and snowboarding (Minnoye & Plettenburg, 2010). Likewise some attention has been paid to the elite athlete physiology (Mujika et al. 2015) but this study did not have the scope to consider the technology specifically used to support the athlete. This aside, three studies have considered the needs of technology used by elite participants. These have included a case study by Riel et al. (2009) which required the creation of a prosthetic arm used by a racing cyclist for the Paralympic Games in 2008. This development considered the needs of multiple sporting disciplines the athlete was due to compete in and had a heavy emphasis on the modularity to switch between these events. Likewise, a new socket design was created for a multi-sport track and field athlete for the 2000 Paralympic Games (Tingleff & Jensen, 2002). Its emphasis was on versatility and competence of its use but not that of a device exclusively seeking to maximise its performance. As a result, this design would likely have been compromised by the need for its sporting event versatility. Finally, a lower-limb prosthesis was developed for an elite paracyclist (Dyer & Woolley, 2017). In this case, whilst its high performance intent was clear, the solution lacked some of the validity needed to justify its design based on its conceded short development timescale. In all three cases, the design process was not clearly described, defined or structured beyond that of identifying the needs and then presenting a final solution. This would make it harder for both practitioners, designers and the athletes themselves to know how to replicate these successes, be aware of the process that they could follow or to identify key factors to increase prostheses performance. However, it has been shown that consideration of a prosthetic limbs design, when optimised, could be a legal form of performance enhancement (Nolan, 2008; Dyer, 2015a). The use and proposal of a model to address these concerns could provide positive guidance to practitioners and directly address the ambiguity and reproducibility issues of previous sports prostheses design projects.

There are several models and frameworks which relate to the development of assistive technology but these are few in number and lack specificity. Some examples of these include the VDI 2242 model which considers the engineering design of products in accordance with their ergonomic needs and then the identification of both its input and output factors when using it (Moritz & Haake, 2006 p18). The input factors are the exercise, movement or activity of the chosen sport or form of recreation. The resulting output factors are made up of the intended effects, the side effects, the feedback effects and the subjective effects. The intended effects would be the desired effects of the equipment's use. However, the side effects may be either positive or negative impacts of the equipment's use and is similar to the Tenner 'revenge effect' (Swierstra & Waelbers, 2012). The feedback effects are the dynamic relationship for an athlete to modify the use of the equipment based upon their sensory response of using it. Finally, the subjective effects are those not grounded in either fact or science but are the athletes emotional response to the equipment's use. These could include the equipment's impact of status, fashion and external perception. There are no accounts of the application of this model when applied to sports assistive technology to date so it is not known whether the models lack of detail would prove problematic.

A similar approach to the VDI model is adopted in a modified 'Classification of Functioning, Disability and Health' framework by Cowan et al. (2012) for the World Health Organisation International. The value of the VDI 2242 model is that it takes a problem-centred approach rather than a solution-driven approach. Likewise, the EMFASIS framework proposed by Plos et al. (2012), suggest that specialized equipment developed for the disabled can still have value universally by utilising a 'top down' approach which can then see its results or value be applied to a broader user market. However, as per the VDI 2242 model, the Plos et al. approach provides a robust underpinning philosophy for the development for such technology but lacks the detail and reproducibility to be useful to health practitioners and engineers when developing performance-centred prostheses equipment. In addition, it could be argued that the Plos et al. is not relevant as it fundamentally adopts a universalist approach. A universalist approach suggests that the design of products should be able to be utilised and accommodated by the largest array of end users or consumers with minimal adaptation. However, it is likely that since an elite athlete is only concerned with their own performance (and not their competition) coupled with the unique nature of a person's disability means that this principle isn't relevant. As per the VDI model, there have been no actual applications of this approach when applied to sports assistive technology to date. As a result, all current models intended for the design of sports technology or the creation of assistive technology lack the detail and application to the design of prosthetic limbs required for competitive sport. This paper will evaluate the current practise surrounding the design of prosthetic limbs, propose a conceptual model that is tailored to this end and then apply it to a relevant case-study. The results of this study will then act as a means of further practical guidance to practitioners (such as prosthetists and biomedical engineers) when creating prosthetics limbs used for sport and recreation.

Proposal of a Hanging Diamond model

The process of engineering design has been summarised and while many of the published models may differ semantically, the basic philosophy behind them is consistent (Howard et al. 2008). The Howard et al. analysis of 23 different design process models revealed that they all typically utilise a six step process from establishing a product need through to its delivery. Therefore, their similarity can provide some margin of confidence in the design of a new model tailored to athletes with limb absence. To address the needs of elite athletes who possess limb absence, a proposed model to assist in the development of assistive technology is proposed in figure 1.

[insert figure 1]

The proposed ‘Hanging Diamond’ model (HDM) in figure 1 utilises a 3 phase process and is a modification of the ‘double diamond’ design process (Design Council, 2006) and the need to combine the separate entities of *form*, *function* and underlying *context* to generate a performance orientated solution (Kalay, 1999). The model itself has also been evaluated within peer-reviewed research and applied to the health and wellbeing aspects of environmental impacts when undertaking a case study approach (Clune & Lockrey, 2014). The double diamond model was developed by analysing how professional designers perform the design process within an industrial setting. The double diamond shape itself is used to illustrate a natural expansion and convergence of the creative process in two separate stages. The first diamond focuses on the project and its underlying research by expanding through *discovery* and then converging by *defining* the project itself. The second diamond expands through a process of *development* as design concepts are created and then converges as the chosen concept is nominated, refined and then delivered, evaluated or produced. However, this model’s intent is philosophical in nature and is not prescriptive in its required tasks. The double diamond also supports that the designing activity is not a linear process and any of its stages can by cyclic in nature but does not illustrate this as explicitly as some methodologies (Howard et al. 2008). It is inferred that the diamond shape allows for a cyclic action within its borders. This does make the model adaptable for use as a means of general problem solving (Clune & Lockrey, 2014) and not just as a means of generating new product designs. As a result, it can easily be modified to suit specific needs but would require further definition and clarification to be useable by practitioners from outside the elite sport environment. The proposed model in this study aims to support this view. In figure 1, the double diamond model is modified by rotating it and that the second diamond is then splintered into two so that the *functional* aspects of a prostheses design are separated and prioritised from those of the *forms* design. This utilises a 'form follows function' design philosophy. This philosophy was coined by architect Louis Sullivan (Russell et al. 2000) and proposed that in the functional design of skyscrapers, that the functional constraints and needs of a building should take priority over its aesthetic needs. This mantra is not universally applied but has been absorbed into conventional design practise discourse (Kalay, 1999). In the case of a prosthetic limb, the fit and functionality are of paramount importance (Legro et al. 1999). However, whilst the form can influence the perception and desirability of a product (Bloch, 1995), these are proposed to be of secondary considerations to the prostheses physical connection to the human body.

Finally, the proposed model then includes indicative activity considerations that are considered worthwhile for prosthetic limb development when in an elite sport context.

Specification phase

The first phase of the proposed framework focuses on establishing the need, opportunity and the context of a product development before any design takes place (Hollins & Pugh, 1990). The Hollins and Pugh approach is incorporated into the model and lays the foundation for product development by primarily performing *product definition*, *competition analysis* and *ascertaining product status* tasks. For example, the demands of cycling can vary based on the events length, topography or the skills required to perform it (Jeukendrup et al. 2000) and these would lead to design solutions that would weight or highlight some prosthetic design needs over others. This would also apply other constraints such as cost, material choice and lifespan. In figure 1, the orientation of the proposed tasks have been rotated vertically along the full length of the diamond to suggest that these straddle the expansion and convergence of this process as the information for each task is sourced and then refined – ultimately leading to its specification. This diamond comprises three indicative activities prior to the products specification and these could be performed in parallel or in any order.

Identification of sports events assistive/resistive factors

The first indicative task identifies the intended sporting events assistive or resistive factors that the athlete is subjected to. These factors could typically be identified by applying a systematic model such as the Hay & Reid Performance Outcome Model (Lees, 2002). The identification of such factors will influence the design and may identify key input that is required from practitioners outside of the typical healthcare sphere. This could lead to design solutions not constrained by tradition or historical preconceptions. Many of the factors that are identified in this phase may well be generic to the sport and particularly to the event itself. For example, a sport such as kayaking would have the assistive factors of paddling forces provided by the kayaker driving them forward yet resistive factors such as the hydrodynamic drag of the kayak shell and the aerodynamic drag of the paddler slowing them down (Michael et al. 2009). Likewise, whilst an athlete with a disability will know which event they wish to perform in, they may not know the nuances or needs that the different lengths or types of that discipline may require. For example, an amputee choosing to run in the 100m sprint runs in a straight line.

However a runner in the 200m is still considered a sprint event (and often sees the same competitors as the 100m event), yet requires the negotiation of a large bend in the track. As a result, both races may require differences in their limb to limb prostheses design based on the reported difficulties of running round the curve of an athletics track (Knight, 2016). In some cases, it is not inconceivable for a resistive factor to contradict an assistive one. In such cases, both views should be taken on balance with the most advantageous effects adopted. As a result, the assistive/resistive factors are indicative in nature and should all be identified but would be accounted for in the product solution at the prosthetic designer's discretion.

Historical performance of analysis of event

The second activity that takes place within the first diamond is the identification of the sports historical performance. This source of context is achieved through the use of statistically-based performance analysis methods. Performance analysis aims to advance our understanding of sports behaviour with a view to improving its future outcomes (McGarry, 2009). The typical scope of performance analysis can include:

- *Notational analysis* – the objective recording of performance so that reliable and objective information can be reviewed (Hughes & Bartlett, 2002). This can involve the analysis of its movement, its technical and tactical evaluation and a statistical compilation of sport, games and competition (James, 2006).
- *Biomechanical analysis* – this can be used within a sport to define the nature of their skills, to gain an understanding of the mechanical effectiveness of their execution and to identify the factors underlying their performance (Lees & Nolan, 1998).

- *Time series and time motion analysis* – the objective review of a sport or athletes performance over a given time period. For example, the evaluation of results records is a reliable means of assessing the capabilities of athletes (Lippi et al. 2008), predict future scope of performances (Dyer & Hassani, 2016) and in some cases can be used to infer and isolate technologically influenced changes in performance (Haake, 2009).

Assess legislative rules and boundaries

The final activity of the first diamond acknowledges the awareness of any constitutive rules that may limit the prostheses design or highlight a possible exploitation of their limitations. Competitive sports utilise a series a rules to ensure fairness or systematically restrict the possible actions of the players and prescribe the aims for the players' actions (Lumer 1995). Taking cycling as an example, the governing body announced that it may well regulate prostheses design in the future (UCI, 2016). Knowing that it currently restricts the depth of aerodynamic frame and component cross sections to a ratio of 3:1 may well help limit innovations in that particular sport. Alternatively, by determining that no rules currently exist to constrain prostheses performance at all, provides the assurances to fully exploit any performance enhancement that exists. For example, the cycling riding positions used by Graeme Obree for his cycling hour record successes during the mid 1990's were considered unconventional (Jeukendrup & Diemen, 1998) and worked to the absolute limits of the rules definitions. Obree had merely identified innovative ways to maximise his performance and whilst these were suggested as being undesirable, his records stood. Whilst the 'spirit of the sport' is used in some cases to rule on whether technology is acceptable (Savulescu et al. 2004), it has been conceded that this is an ideal (McNamee, 2012) so therefore relative in nature and limited in its practical application

Functionality phase

The second hanging diamond denotes a functional design phase. This phase focuses on creating a prosthetic limb that can specifically satisfy the ergonomic and biomechanical needs of the athlete or end user. This process will start with the conceptualisation and a subsequent range of potential solutions (Howard et al. 2008). After this step has been completed, a smaller number of potential solutions are tested through prototyping or simulation in a sports-specific context. When taking a view of sports equipment development in general, it is proposed that the testing or development of any solutions should utilise the scale and magnitude of observed loads and frequencies (Dabnichki, 1998) and it is key that the design solution of assistive devices for athletic activity should depend on the sport itself. This would ensure that any findings are tailored as much as possible to the specific sporting endeavour the athlete intends to compete within. For example, in the case of swimming, the athlete would test a prosthesis prototype at the physiological intensity they would typically compete at, in a swimming pool and using the stroke they intend to use. These tests would then report the results – both quantitative and qualitative in nature. After such trials and simulations, the best solution is selected and is then refined so that it can be manufactured. The final step is then to optimise this functionality. This is whereby the criteria and design objectives identified in the first phase (both the assistive and the resistive factors) are further optimised. For example, this could mean a further reduction in prosthetic mass to improve a power to weight ratio if cycling, further reductions in fluid hydrodynamic drag to increase the athlete’s velocity when swimming or greater increases in energy return to improve running performance. It is this optimisation phase that separates equipment designed purely to facilitate an athlete's participation within a sport to those who wish to maximise their performance within it.

Form phase

Once the functional design has been defined, the model then moves to its third and final diamond. This diamond considers the prosthesis form. The considerations and needs of a prostheses form can be broad in nature. For example, this could involve changing the physical form to increase aspects such as its aerodynamic performance (Dyer, 2014) or altering its form to manipulate its emotional response (Sansoni et al. 2016). In addition, attention to the form of a product has been indicated to affect the level of emotional attachment or significance to its end user (Mugge et al. 2009). Superficially this could involve decorative-based changes or more substantive aesthetic changes due to the end users likes or dislikes. However, such needs would need to be balanced carefully against any penalties to actual physical performance. To date, the form considerations of sports prostheses design has only been noted informally (Dyer, 2013) and the specific emotional relationship of athletes to their technology has not yet been explored. As a result, this field within the prostheses design process requires further attention.

Once the design has been conceptualised and applied to the functional design, context specific field trials are conducted again to evaluate the design(s). Finally a phase of optimisation of the physical form takes place if needed. As per the functional design phase, the process within this diamond may be cyclic and non-linear.

After the form phase has been concluded, the final design will be realised or alternatively, a series of design prototypes may then be evaluated against each other to select the best solution.

Application of the HDM: a case study

The proposal of the HDM would is further evaluated through its application to a case study. This case study had been preceded by a similar project that took place four years prior that did not utilise a structured design model and was felt to lack reproducibility (Dyer, 2013).

This case study was a male, elite- level cyclist who possessed a trauma-originated transtibial amputation. The participant was aged 33, had a height of 1.72m, a weight of 73kg and had personal best cycling performances including 21 minutes and 31 seconds for a 16.1km individual time trial and 3 minutes and 56 seconds for the 3km individual track pursuit. The intended use of the prosthesis was for road and track cycling events at the Paralympic and Invictus Games. The prostheses would be worn only when cycling and would be used when the athlete rode in an upright conventional riding position as well as when adopting an aerodynamic 'tuck' position on their bicycle. Whilst it might seem appropriate to use a multi-purpose prosthetic design (so that they could move easily around when not cycling) this would likely not prioritise the key performance needs of competitive cycling. This project received institutional ethics committee approval.

Specification phase

This phase defined the need and specification of the scope of the prosthetic device. This need was established when the athlete had already approached their practitioner prior to its design. The uses of the device (such as the sports events) were outlined. The athlete required a prostheses to undertake outdoor road based time trials, road-based bunch racing and track racing. These sports disciplines formed the basis for the underlying research for the next phase initially via a literature review.

Identification of sports events assistive/resistive factors

A review of the scientific literature and construction of a Hay & Reid Performance Outcome Model revealed that the two sports-specific key consistent design needs of cycling equipment were the reduction of its *aerodynamic drag* and any improvement of the power to weight ratio of the cyclist (Dyer and Woolley 2017). Aerodynamic drag of a cyclist can represent up to 96% of the riders applied power at their typical racing speeds (Dyer and Disley, 2017) whereas a reduction in mass would improve the riders acceleration from rest when starting or when choosing to accelerate. However, since the cyclist was also an amputee, it meant that the designers could optimise the form of the leg in ways that couldn't obviously be achieved with a biological limb.

A desired improvement in the power to weight of the device was achieved by discussing the prostheses materials and construction methods and seeking weight savings where possible by minimising material where it was not required. Further details of the construction methods utilised for such applications have been defined before (Dyer and Woolley 2017).

Historical performance of analysis of event

The next phase was to investigate what scope for performance improvement existed within cycling. Firstly photographic and video evidence of the athletes' typical competitors revealed that few of these were using an optimised or cycling-specific prosthetic limb design. Secondly, an analysis of the results at the Paracycling Track World Championships from 2011-16 demonstrated that uni-lateral below-knee amputees were typically grouped in the same classification as athletes who possessed other forms of disability. Further statistical analysis also revealed that those requiring the use of prosthetics technology were not statistically significant to those without such devices. However, those utilising a prosthetic limb would typically achieve a superior finishing position to those who did not. This demonstrated to the athlete that by focusing on key cycling disciplines may provide better or alternative opportunities for perceived success. A fuller analysis of this investigation is covered in Dyer (2017).

Assess legislative rules and boundaries

This phase considered the existing rules and legislation of competitive cycling and to ascertain what might be needed to be taken into account when designing the limb itself. A search of the relevant literature revealed that no specific legislation applied to the prosthetic limbs design at all. However, it was noted that the world cycling governing body (the UCI) had determined that all prostheses used for para-cycling competition needed to be formally approved for use from 2014. Anecdotally, it was felt that the UCI was becoming concerned over the use of increasingly advanced prostheses designs. As a result, the design team agreed to consider the governing body's general bicycle equipment rules that defined that the frame tubes would not exceed a 3:1 width-to-depth ratio. This decision would mean that the prostheses would not appear visually 'out of step' with the other equipment that they would typically use or be at risk of drawing unwanted scrutiny when in the competitive arena (whereby the athlete should likely be focused on their performance) (Dyer 2013).

Functionality phase

The starting point for the prosthesis functionality aspects was to determine its required length and geometry and this was achieved by getting the athlete to ride their own racing bicycle when mounted on a stationary trainer. This allowed biomechanical changes to be made in a controlled environment but with the athlete using the specific equipment and riding position they intended to race with. This provided a level of specificity to any testing, assessment or analysis. Whilst their biological limb could normally act as a good form of comparison, their lack of an ankle on the amputated side meant a completely symmetrical pedalling action would not be achievable. Instead, an adjustable prosthesis was used and adjusted incrementally to obtain an overall geometry and fit that provided the greatest level of comfort to the athlete. During this, the athlete was asked to ride a series of timed intervals at intensities that were typical of their racing. The reason for this was that the level of limb to limb symmetry and the biomechanical behaviour of an athlete will vary based on their exercise intensity or effort. Once the most powerful and comfortable riding position was achieved, the adjustable prosthesis had its measurements recorded and these would form a firm specification of the prosthesis design that would then not be altered by the prostheses form phase.

Form phase

As noted earlier, aerodynamics was judged to be of prime importance in this prostheses design. As a result, as series of concept designs would be evaluated using a cost-effective validated method of aerodynamic field testing (Dyer and Disley, 2017). The design with the second lowest aerodynamic drag penalty was selected. The reason for this was the that the best solution utilised an aspect ratio far greater than 3:1, it was felt that this would be more sensitive to the socket/stump alignment than a slightly shallower design and may be perceived negatively by the governing body. Secondly it was felt that the second design aerodynamic drag penalty over the best one was marginal but would visually appear to be a more covert device thereby supporting the needs raised in the legislative rules and boundaries phase.

The form was not further modified such as improving the user's attachment to the product as proposed by Mugge et al. (2009). At this point, no study had evaluated how sporting performance could be improved by doing so and the timescales of the project did not allow for such an investigation to be able to take place at this point.

Discussion of the models application

This paper builds on previous knowledge as it is the first such study to create a model for the development of an athlete's prostheses technology. The model is unique as it draws on diverse and multidisciplinary themes that are far broader in scope than the few studies that have been published to date have considered. However, this uniqueness of the model may create some potential barriers as to its adoption as its broad and multidisciplinary nature may mean that the traditional prosthetic limb developers may not possess (or have access to) all of the skills required to fulfil it. A potential solution may mean that such projects may require the utilisation of design teams possessing multiple members to then accommodate these skillsets.

Reflection on the HDM

Whilst the HDM uniquely separated both form and functional design requirements, it was felt after the case study that the potential of the prostheses *form* development was potentially unfulfilled or underdeveloped. In the case study, the form was dominated by the aerodynamic considerations of the function phase. This was to be expected when the HDM utilised a 'form follows function' ethos. However, this meant that there was less emphasis in incorporating alternative approaches and benefits such as product attachment or user customisation (Mugge et al. 2009) or a controlled adoption of the placebo effect (Bérdi et al. 2011). By doing so could potentially broaden, deepen and potentially strengthen prosthetic limb design and its subsequent performance. For example, the inclusion of the athletes favourite colour on their prosthetic limb design has drawn positive feedback from an athlete (Yamanaka et al. 2011) and the use of painted striping improved the paddling biomechanics of a rower by manipulating the athletes visual perceptions (Millar and Oldham 2016). This suggests that form aspects can interact directly with functional outcomes so whilst both are focused on separately, they should not be completely ring-fenced from each other. Either way, these examples may not be typical considerations when undertaking traditional sports engineering yet offer end-user value.

Whilst the HDM model provides some guidance for the design process, its actual suggested actions for each phase remain suggestive, indicative but not exhaustive. This means that there are design activities that may still be missed by some practitioners due to them not being aware that they exist. However, this same issue is more severe in other design process models such as the VDI 2242 or the EMPHASIS models discussed previously. Ultimately, more applications of the HDM will attempt to address any shortcomings in its perceived content through further case study's and subsequent knowledge transfer. It would be helpful if future revisions of the proposed model should include an increasing list of indicative design methods to assist practitioners once more case studies have been conducted. This would also highlight more clearly the need to commit more members or resources to the design team if it did not feel such activities could be accommodated using its existing skillset and membership.

Model validity and reproducibility

The reproducibility of the HDM process may prove challenging due to the bespoke and unique nature of prosthetic limb design used for sport (Bragaru et al. 2012). Further case studies are required to fully validate the model to a sufficient level but the relatively limited numbers of athletes with limb absence may mean this could some time to establish. In the short term, it may well be more prudent to focus on the measurable and scale impact of each projects outcomes.

The validity of this model cannot be stated quantitatively. However, it is felt that the proposed model does possess validity as the double-diamond model (that acted as its foundation) was derived from both informed professionals and peer-reviewed design philosophy as well as ultimately being applied to a case study (Clune and Lockrey 2014). The sports-based specificity aspects of the HDM could be considered valid by judging each phase on its own merits. In the case of the specification and identification of sports events assistive/resistive factors phases, the needs to specify a product before it is created would seem to be self-evident and is a cornerstone of establishing the product need for most proposed models of the creative design process (Howard et al. 2008). Likewise, the form and functional considerations are also fundamental design taxonomies in product design (Veryzer 1995). However, it was conceded within the case study of this paper that the application of form design considerations (when applied to competitive sport) requires further development and investigation.

Validity of the performance analysis of an event has been extensively supported (Hughes and Bartlett 2002) and has been applied to sport with limb absence with measurable impacts on how its technology should be viewed (Hassani et al. 2015; Dyer 2017).

Finally, the legislative rules and boundaries considerations were included as a means to support the specification phase but also to identify and to exploit any potential competitive advantage through the circumnavigation or the exploitation of the rules of a high performance sport. This practise is not unusual and is indicative in other high-performance sports such as Formula 1 motor racing (Amis et al. 1997).

Ultimately this project should be judged by its outcomes. In the case study provided here, the new design provided significant time savings to the athlete in their cycling time trial track events that could potentially elevate them into a medal winning position (Dyer & Disley 2017). The proposed HDM models use was integral to this end and the experience in this paper suggests that it is transferable in its scope and definition to be used with other forms of competitive sports technology and not just the design of prosthetic limbs. The HDM model is recommended to be applied to other case studies and have its validation strengthened based upon those experiences.

Conclusion

The proposed hanging diamond model provides a framework to design and develop a competitively oriented prosthetic limb for athletes who possess some level of limb absence. The advantages of this framework are that it provides guidelines and considerations in a field of study that has seen very little attention historically but will have increasing importance as sporting performance improvements continue to be sought out. Whilst currently limited in number, some studies have revealed that the potential grounds exist for assistive technology to provide a mechanical ergogenic effect. The proposed hanging diamond model is designed to support this ambition. Confidence of the proposed models design can be provided in that its philosophy adopts contemporary product design methodology that was obtained from both peer reviewed research and the utilisation of industrially based-practitioners. The proposed model was applied to a case study and the outcomes of which obtained measurable performance enhancement. The model is recommended to be applied to other case studies and have its validation strengthened based upon those experiences.

References

Amis, J., Pant, N. & Slack, T. (1997). Achieving a sustainable competitive advantage: A resource-based view of sport sponsorship. *Journal of sport management*, 11, 80-96.

Bérdi, M., Köteles, F., Szabó, A. & Bárdos, G. (2011). Placebo effects in sport and exercise: a meta-analysis. *European Journal of Mental Health*, 6, 196.

Bloch, P. (1995). Seeking the ideal form: Product design and consumer response. *The Journal of Marketing*, 16-29.

Bragaru, M., Dekker, R., & Geertzen, J. (2012). Sport prostheses and prosthetic adaptations for the upper and lower limb amputees: an overview of peer reviewed literature. *Prosthetics and Orthotics International*, 36, 290-296.

Clune, S, & Lockrey, S. (2014). Developing environmental sustainability strategies, the Double Diamond method of LCA and design thinking: a case study from aged care. *Journal of Cleaner Production*, 85, 67-82.

Couture, M., Caron, C. D., & Desrosiers, J. (2010). Leisure activities following a lower limb amputation. *Disability and Rehabilitation*, 32, 57-64.

Cowan, R. E., Fregly, B. J., Boninger, M. L., Chan, L., Rodgers, M. M., & Reinkensmeyer, D. J. (2012). Recent trends in assistive technology for mobility. *Journal of Neuroengineering and Rehabilitation*, 9, 20.

Dabnichki, P. (1998). Biomechanical testing and sport equipment design. *Sports Engineering*, 1(2), 93-105.

Deans, S., Burns, D., McGarry, A., Murray, K., & Mutrie, N. (2012). Motivations and barriers to prosthesis users participation in physical activity, exercise and sport: a review of the literature. *Prosthetics and Orthotics International*, 36, 260-269.

Design council, (2006). Double diamond design. http://www.designcouncil.org.uk/sites/default/files/asset/document/ElevenLessons_Design_Council%20(2).pdf accessed 8/12/16

Dyer, B. (2017). The impact of lower-limb prosthetic limb use in international C4 track para-cycling. *Disability and Rehabilitation: Assistive Technology*, 1-5.

Dyer, B. and Disley, B.X. (2017). Validation of the virtual elevation field test method when assessing the aerodynamics of para-cyclists with a uni-lateral trans-tibial amputation. *Disability and Rehabilitation: Assistive Technology*, 1-5.

Dyer, B. & Woolley, H. (2017). Development of a high-performance transtibial cycling-specific prosthesis for the London 2012 Paralympic Games. *Prosthetics and Orthotics International*, 0309364616682386.

Dyer, B., Hassani, H., & Shadi, M. (2016). The analysis and forecasting of male cycling time trial records established within England and Wales. *Journal of Sports Sciences*, 34, 1222-1230.

Dyer, B. (2015a). The importance of aerodynamics for prosthetic limb design used by competitive cyclists with an amputation: An introduction. *Prosthetics and Orthotics International*, 39, 232-237.

Dyer, B. (2015b). Cycling with an amputation: A systematic review. *Prosthetics and Orthotics International*, 0309364615610659.

Dyer, B. (2013). 'Scribble, Sketch, Carve, Wrench and Spin': A Case Study of a Paralympian's Cycling Prostheses Design. *In: UK High Performance Conference for Paralympic Sport Science and Sport Medicine* 21-22 May 2013 Burton Upon Trent, United Kingdom.

Gailey, R., & Harsch, P. (2009). Introduction to triathlon for the lower limb amputee triathlete. *Prosthetics and Orthotics International*, 33, 242-255.

Gold, J. R., & Gold, M. M. (2007). Access for all: the rise of the Paralympic Games. *The Journal of the Royal Society for the Promotion of Health*, 127, 133-141.

Haake, S. J. (2009). The impact of technology on sporting performance in Olympic sports. *Journal of Sports Sciences*, 27, 1421-1431.

Hassani, H., Ghodsi, M., Shadi, M., Noroozi, S. and Dyer, B. (2015). An Overview of the Running Performance of Athletes with Lower-Limb Amputation at the Paralympic Games 2004–2012. *Sports*, 3, 103-115.

Hollins, B., & Pugh, S. (1990). *Successful product design: what to do and when*. Butterworth-Heinemann.

Howard, T. J., Culley, S. J., & Dekoninck, E. (2008). Describing the creative design process by the integration of engineering design and cognitive psychology literature. *Design Studies*, 29, 160-180.

Hughes, M. D., & Bartlett, R. M. (2002). The use of performance indicators in performance analysis. *Journal of Sports Sciences*, 20, 739-754.

James, N. (2006). Notational analysis in soccer: past, present and future. *International Journal of Performance Analysis in Sport*, *6*(2), 67-81.

Jeukendrup, A. E., Craig, N. P., & Hawley, J. A. (2000). The bioenergetics of world class cycling. *Journal of Science and Medicine in Sport*, 3, 414-433.

Jeukendrup, A., & Diemen, A. (1998). Heart rate monitoring during training and competition in cyclists. *Journal of Sports Sciences*, 16(sup1), 91-99.

Kalay, Y. E. (1999). Performance-based design. *Automation in Construction*, 8, 395-409.

Legro, M. W., Reiber, G., del Aguila, M., & Ajax, M. J. (1999). Issues of importance reported by persons with lower limb amputations and protheses. *Journal of Rehabilitation Research and Development*, 36, 155.

Lippi, G., Banfi, G., Favaloro, E. J., Rittweger, J., & Maffulli, N. (2008). Updates on improvement of human athletic performance: focus on world records in athletics. *British Medical Bulletin*, *87*(1), 7-15. McGarry, T. (2009). Applied and theoretical perspectives of performance analysis in sport: Scientific issues and challenges. *International Journal of Performance Analysis in Sport*, 9, 128-140.

McNamee, M. J. (2012). The spirit of sport and the medicalisation of anti-doping: Empirical and normative ethics. *Asian Bioethics Review*, 4, 374-392.

McQuarrie, K. M., Atterås, K., & McGarry, A. (2015). Design of Prosthetic Components for Skiing: A Preliminary Study. *JPO: Journal of Prosthetics and Orthotics*, 27, 154-160.

Knight, K. (2016). Paralympic sprinters' prostheses impair curve-running performance. *Journal of Experimental Biology*, 219, 769-769.

Lees, A., (2002). Technique analysis in sports: a critical review. *Journal of Sports Sciences*, 20, pp.813-828.

Lumer, C. (1995). Rules and moral norms in sports. *International Review for the Sociology of Sport*, 30(3-4), 263-280.

McGarry, T. (2009). Applied and theoretical perspectives of performance analysis in sport: Scientific issues and challenges. *International Journal of Performance Analysis in Sport*, *9*(1), 128-140.

Michael, J. S., Smith, R., & Rooney, K. B. (2009). Determinants of kayak paddling performance. *Sports Biomechanics*, 8, 167-179.

Millar, S.K. & Oldham, A. (2016). Optimising repeated interceptive performance using contrasting visual textures in Olympic rowing: A case study. *Sensoria: A Journal of Mind, Brain & Culture*, 12.

Minnoye, S. L., & Plettenburg, D. H. (2009). Design, fabrication, and preliminary results of a novel below-knee prosthesis for snowboarding: A case report. *Prosthetics and Orthotics International*, 33, 272-283.

Moritz, E. F., & Haake, S. (2006). *The Engineering of Sport 6*. Springer.

Mujika I, Orbañanos J, & Salazar H. Physiology and Training of a World Champion Paratriathlete. *International Journal of Sports Physiology and Performance*. 2015 Feb 11.

Mugge, R., Schoormans, J.P. & Schifferstein, H.N. (2009). Emotional bonding with personalised products. *Journal of Engineering Design*, 20, 467-476.

Nolan, L. (2008). Carbon fibre prostheses and running in amputees: a review. *Foot and Ankle Surgery*, 14, 125-129.

Plos, O., Buisine, S., Aoussat, A., Mantelet, F., & Dumas, C. (2012). A Universalist strategy for the design of Assistive Technology. *International Journal of Industrial Ergonomics*, 42, 533-541.

Riel, L., Adam-Côté, J., Daviault, S., Salois, C., Laplante-Laberge, J., & Plante J. Design and development of a new right arm prosthetic kit for a racing cyclist. *Prosthetics and Orthotics International*. 2009, 33, 284-91.

Russell, B., Motlagh, D., & Ashley, W. (2000). Form follows function: how muscle shape is regulated by work. *Journal of Applied Physiology*, 88, 1127-1132.

Sansoni, S., Speer, L., Wodehouse, A., & Buis, A. (2016). Aesthetic of prosthetic devices: from medical equipment to a work of design. In *Emotional Engineering Volume 4* (pp. 73-92). Springer International Publishing.

Santana, F. E., Junior, I. R. M., Catapan, M. F., Batista, V. J., & Forcellini, F. A. (2016). Opportunities and Challenges on Assistive Technology Innovation: a Systematic Literature Review on People with Disabilities. *International Journal of Knowledge Engineering and Management* , 5, 92-115.

Savulescu, J., Foddy, B., & Clayton, M. (2004). Why we should allow performance enhancing drugs in sport. *British Journal of Sports Medicine*, 38, 666-670.

Swierstra, T., & Waelbers, K. (2012). Designing a good life: A matrix for the technological mediation of morality. *Science and engineering ethics*, 18, 157-172.

Tingleff, H., & Jensen, L. (2002). Case report: A newly developed socket design for a knee disarticulation amputee who is an active athlete. *Prosthetics and Orthotics International*, 26, 72-75.

UCI. (2013). Paracycling: Integration and Approval. *Update Sport and Technical*, 6:9.

Veryzer R. (1995). The place of product design and aesthetics in consumer research. *Advances in Consumer Research*, 22, 641-645.

Yamanaka, S., Tsuji, Y., Higaki, M. & Suzuki, H. (2011), Designing the sports prosthetic leg. In *Proceedings of the 2nd Augmented Human International Conference* (p. 15). ACM.