Australasian Medical Journal 2009, 1, 11, 152-3

Developing Tomorrow's Innovative Surgical Solutions

Philip Breedon
Nottingham Trent University
UK

Editorial

Please cite this paper as: Breedon P. Developing tomorrow's innovative surgical solutions. AMJ 2009, 1, 11, 152-3. Doi 10.4066/AMJ.2009.164

Designers are increasingly becoming aware of the potential use and integration of *smart* materials and technologies within their designs. One of the critical steps towards building innovative surgical solutions will be to link physicians and product designers utilising the appropriate materials and technologies to provide tangible improvements in patient care and treatment.

A designer will have undergone extensive visual training providing them with a unique skill set to scrutinise and then apply their critical vision to a creative process. Designers are trained to think three-dimensionally about form. In creating a new medical device, designers must understand the complex set of issues that exist in a variety of environments. It also illustrates the need for designers to understand a wide range of styles and techniques and transform ideas and visions into new pioneering products ready for market. For example due to the nature of the orthopaedic surgical process clinical observation by designers is critical for creating orthopaedic devices and implants.

Within the medical context design projects can follow user centred design, participatory design and scenario based design methodologies, however user capabilities and preferences will be extremely varied, the position of the user is essential as part of the design process.

The knowledge and experience of the user must be taken into account during the design process. For medical equipment the design client, procedure and product should be considered in order to gain a better understanding of specific design requirements. A design methodology should be specified based on comparative and multiple design parameters providing alternative proposals for the improvement and adaptation of the design process.

Often the lack of any design process methodology can create at a minimum frustration for the surgeon and surgical team for bespoke clinical devices. Effective communication between the manufacturer and physician may not always be evident.

The development of a Product Design Specification (PDS) comprises a quantitative statement of user requirements in relation to commencing a design. The specifications outlined in the PDS should be largely autonomous of any specific representation of the product to allow for multiple concept design solutions. A PDS will ensure that a design will actually address the appropriate customer needs; an essential attribute if the product is to be successful. By developing multiple design concepts that contrast and compare the multiple attributes that must be accommodated in the final design. The introduction of a Design weighted matrix allows weighting factors to be utilised to define the level of importance of specific design criteria. Assigning significance to weighting factors is subjective. Responsibility should be given to the physician and/or clinician to determine the importance of each criterion by assigning weight factors and to understand the compromises when assigning weight factors.

Interaction at this level means the designer can not only react promptly to current market variance but can liaise with surgeons to develop products that will meet and potentially surpass their requirements. This interaction must be combined with a high level of design and manufacturing expertise, ensuring the ability to produce innovative medical design and patient solutions.

The importance of human aspects in industrial environments has changed the viewpoints of designers and as a result Human-Centred design approaches have been developed. One of the fundamentals of this approach is to consider human factors at each stage of the design process. A commitment to involve and understand the intended user is essential to the design process, for a user to understand the product you must initially understand the user.

A user centred design approach as an adapted design methodology can provide real benefits in terms of medical product design. Orthopaedic device design and development provides a good example. Orthopaedic devices must be designed to accommodate dynamic environments and varied surgical processes. In addition, meeting with the surgeon to discuss spatial relationships and provide the opportunity to touch the instrument can provide useful verbal feedback. To aid this process the production of a 3D model, which can be modified quickly and easily, allows the development of a range of fabricated models for a single device specification. Fused deposition modelling (FDM) is an additive manufacturing technology commonly used for modelling, prototyping, and production applications. Also known as Rapid Prototyped (RP) models these models are manufactured from Computer Aided Design (CAD) models, the CAD model incorporating the key device attributes specified by the surgeon.

Another important aspect of surgical device design is to define the parameters associated with dimension, overall function and other device variables in perspective, and to use this information to design a device that complements surgical technique. This process includes kinaesthetic learning or intelligence from or within the clinical environment and incorporating this intelligence into the design concepts.

A rather simplistic but good example of the lack of any design process was raised when discussing surgical tools and procedures with a neurosurgeon. The use of a laser can reduce the complications in any sort of intracranial surgery. Laser safety glass worn by the surgeon attempts to filter out the wavelength or wavelengths used by a laser, whilst at the same time attempting to maximize the Visible Light Transmission (VLT). However the reality in many instances is that laser filter lenses have less than perfect VLT and often add a colouration that affects the surgeons' ability to see all colours clearly and correctly. A laser safety glass face shield was worn by the surgeon when using the laser for invasive procedures and to control residual bleeding. The laser glass specified and utilised in the face shield meant that the surgeon could not identify any cranial bleeding without lifting the shield. Clearly a human centred design approach had not been adopted by the manufacturers.

It can be difficult within the UK to access the appropriate personnel within the National Health Service (NHS) who can help universities and companies to design and develop the next generation of products to improve patient care and develop new products. In addition medical research is often too focussed where researchers are uncomfortable or not prepared to step outside their specialised areas of research. Amongst other initiatives the introduction of knowledge transfer partnerships with universities, information networks and specialist company links with the NHS is beginning to address these issues. In addition, the Design Council has launched a number of initiatives and commissioned a number of reports including, 'Design Bugs Out', 'Design for Disability' and 'Design for Patient Safety'.

Perhaps most importantly the introduction and establishment of the appropriate industrial design links with healthcare networks is essential for the effective and efficient development, design and manufacture of innovative surgical devices. These initiatives will allow physicians, designers and manufacturers to work more closely together, to share their visions and ideas and provide opportunities to explore and integrate new materials and technologies within their designs.

PEER REVIEW
Not commissioned; Not externally peer reviewed