CUSTOMISED RAPID MANUFACTURED PARTS:
TECHNOLOGY AND CASE STUDIES FROM THE CUSTOM-FIT PROJECT

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Abstract

The design and manufacture of individually customised products is generally restricted to bespoke clothing or footwear for very wealthy customers. The aim of the Custom-Fit project was to develop a fast, flexible and economically viable route for the manufacture of individually customised parts. These products not only provide improved comfort levels but also provide better functional performance, including enhanced safety for the user. This 4.5 year, European Commission subsidised €16 million project, supported by the EU, involving 30 partners across the breadth of the Europe finished in early 2009. This paper will showcase the technology developed: CAD packages which automate the design process and three new rapid manufacturing methods. It will also include case studies on a range of customised products, including customised Motorcycles helmets. The case studies not only demonstrate the performance benefits of individual customisation but also show the potential for new approaches to product design. More information at www.Custom-Fit.org

1. Introduction

Customisation has traditionally been the preserve of the rich or medically unfit, primarily due to the cost of customized products which are often in the order of several thousands of dollars. The driving force behind the European Custom-Fit project (2004 to 2009) was to deliver customised products at an affordable price and thus embody the concept of mass customization as proposed by Tseng and Jiao (2001) "to produce goods and services to meet individual customer's needs with near mass production efficiency". To achieve this objective the project examined and proposed solutions across a wide spectrum of customization challenges including: business implications, technical capabilities (data capture, automated design, rapid manufacturing) and regulatory issues. The findings of the research were validated within the context of six case studies on products for use on or within the body namely: helmets, toy vehicle, motorcycle seats, knee implants (tibial plates), mandibular implants, and transfemoral prosthetic sockets.

Below is a list of the customisation challenges identified prior to and during the early stages of the Custom-Fit project. The list was compiled from several sources including Wimpenny *et al.* (2000), Hague *et al.* (2003), Feenstra et al. (2003), coupled with the experience of the consortium members. The challenges of customisation include:

- Accurately quantifying a market for customisation
- Cost-effectively collecting personal data
- Cost-effectively modifying a product design to a personalised shape
- Verifying the new design is fit for purpose and safe to use in a non-destructive way
- Reliably producing parts
- Delivering ALM (Additive Layer Manufacture) products with superior material properties & performance
- Producing parts with better surface finish

- Manufacturing parts faster
- Certifying that a component is compliant with appropriate standards and regulations

This paper first explores the business implications of customised products establishing evidence of a potential market value. Next, the technical aspect of the work will be considered and finally the regulatory issues will be reviewed.

2. The Challenges of Customisation to Business

The difficulties of successfully building a business around mass customised products are not insignificant. One of the core difficulties is quantifying the added value of customising. Compounding this challenge is the fact that often much of the potential market has never experienced a customised product. Therefore the challenge becomes accurately anticipating the perceived value a customer places on a customised product without any tangible way for them to evaluate it. The need to measure intangibles, including the competitive advantage of customising, customer trust in a brand, and belief in an innovation has been highlighted by researchers, but to date there is no definitive predictor. (Helms *et al.*, 2008; Dewan *et al.* 2000). Even companies accustomed to customising can struggle to anticipate demand accurately (Piller, 2008).

The Custom-Fit project undertook market research in the form of an online survey to establish the market demand for customised motorcycle seats. Ong *et al.* (2008) have published the results of the survey which summarize the responses of over 3000 individuals, mostly men (almost 98%). The survey found that less than 8% of motorcycle drivers share their bike with other riders. 92% of riders experience some discomfort from their seats when travelling long distances. Over 80% of responses favoured the idea of a customised motorcycle seat and were willing to pay more for it (66% up to 250 Euros and 30 percent up to 500 Euros).

Based on the results of the above Custom-Fit survey (Ong et al. 2008) one can extrapolate the potential European market value. If eight million (approximately two-thirds of the European motorcycle riders) bought a customised seat at 250 Euros the market would be valued at 2,000,000,000 Euros. Even taking a very conservative view of the survey results and suggesting that perhaps only one percent of the riders would actually buy a customised seat then the market value is still 2,000,000 Euros. While these numbers are wildly speculative, the interest demonstrated in the survey is clear and suggests that there is a market for customised motorcycle seats.

3. The Custom-Fit Approach

The Custom-Fit project approached customisation from a simple paradigm: Use customer data to automate the design and manufacturing chain of customised parts for use on or inside the body (Jones and Wimpenny 2008). The mass customising of garments illustrates the effectiveness of this philosophy where individual measurement information can be integrated to adapt generic patterns which drive the manufacturing process (Helms, *et al.* 2008). While this approach is well developed and automated in applications where designs are typically two-dimensional (2D) such as the garment industry, the adoption of this philosophy for three-dimensional (3D) products has been limited primarily due to the need for human intervention at the data capture and design stages. Implicit in the scope of this work was to develop a set of software tools to automate a generic 3D design chain competent across a wide variety of products. Each step in the design and manufacturing chain will now be considered as shown in Figure 1.
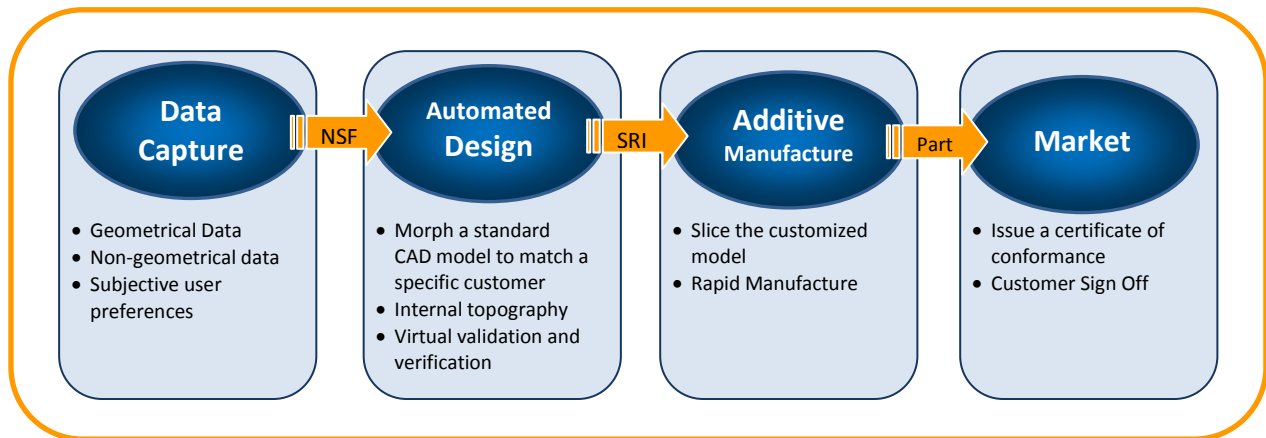
Figure 1 - The Custom-Fit Approach

3.1 Data Capture

The backbone of customer-centric design is to effectively collect as much relevant data as possible from the customer. In the last decade the advances in 3D shape measurement and capture have played an increasingly important role in a variety of fields including manufacturing and medical sciences (Zhang, 2009). 3D non-contact laser scanning was adopted as a standard approach for all products except the implants (VITUS scanner solution by Human Solutions www.human-solutions.com) to quickly (less than 10 seconds) and efficiently capture the shape of customers for the design of customised products. In addition to the physical shape of customers the helmet and

Figure 2 - Comfort Questionnaire

motorcycle seat products required pressure distribution information which was captured using an array of pressure sensors integrated into a flexible "blanket" (X3 PX100:18.18.01 seat sensor by XSENSOR Technology www.xsensor.com). The last type of data collected was subjective. Through a series of questionnaires (developed by the Instituto de Biomecánica de Valencia www.ibv.org) the customer identifies areas on the body of pain or discomfort and assigns a magnitude as shown in Figure 2. This data can then be used within the design process and also for product evaluation. The final need addressed under the data capture umbrella is the ability to package it in a file format that can be readily used by other software tools in an automated way. The shortcomings of point cloud, meshes, and other scan formats has been identified by various researchers (Wand, *et al*., 2008; Stroud and Xirouchakis, 2000). Additionally, the scope of applications required a more universal container file capable of holding customer details, 3D mesh data, DICOM data, pressure maps, and customer preferences. The consortium found the need to establish a new file format for exchanging data between software applications. The new file format is called the Neutral Scanning Format (NSF) and is a container capable of holding a wide variety of data types in XML format.

3.2 Automated Design

Once the NSF file was filled with customer data it the automated design process begins. Custom-Fit built its design automation approach on the concept of "reuse" as originally proposed by Prieto-Diaz (1993) and later reinforced by Tseng and Jiao (1997). Most of the design is "reused" or recycled for each product and only the features that are in contact with the customer during use are customised. Therefore the first step of the design process was to select a base design for further customisation. The 3D scan data was interrogated to establish a match with the closest standard product model available. Next the scan was oriented within the same coordinate system as the standard CAD model so that there was a small gap or overlap between them. The standard product was then morphed or a Boolean operation was performed to conform exactly to the scanned shape.

Having achieved a customised form, the next focus is on enhancing the functionality through modification of the mechanical properties of the product. This is achieved through functional grading of the materials used and/or employing internal lattice structures. The knee implant and prosthesis used the former and the mandibular implant, helmet and motorcycle seat used the latter. Finite element analysis and a design approach were used to establish how the materials or lattice structures should be distributed.

Once the internal and external customisation of product is completed the performance under service conditions needs to be checked. The consistency of approach and reliability of the output is one of the criterions that distinguish mass customisation from craft production (Piller, 2004). For that reason each design created by automated design tools is tested with FEA or FEA established bandwidths prior to manufacture. In this way the high variety of designs can cost-effectively be validated.

3.3 Additive Manufacture

Once a validated design was completed it was then advanced on to the manufacturing stage. As is typical with additive manufacture the models were sliced in preparation for a build. Where graded materials had been assigned to a design STL files could not hold all of the relevant information so a slicing methodology known as a Slice Raster Interface (SRI) format was developed so that assigned material distributions could be translated into a stack of multi-coloured bitmap slices where each colour corresponded to a different build material.

Throughout the project new designs were validated to extent possible using existing RP/RM (Rapid prototyping/manufacturing) systems, however as the project drew toward conclusion and the capability of the three new RM systems increased the production of parts shifted toward the new systems. An explanation of the new systems follows in the next section.

3.4   Market

Careful consideration must be given to the development of a robust methodology for testing of customised products to ensure that they comply with safe performance criteria. For example According to UN regulations no.22, a motorcycle helmet has to pass a series of 12 tests before it is considered "suitable". Fortunately, in many cases customised products offer higher levels of user safety than mass produced products. For example, a poorly fitting motorcycle helmets can give discomfort leading to higher levels of rider fatigue and reduced concentration. Moreover, a customised helmet should ensure more effective distribution of impact stresses across the rider's

skull. The precise testing methodology depends to some extent on the nature of the product but may be based on a combination of empirical tests and computational simulation (this is discussed in more detail in section 7).

In addition to meeting safety performance requirements it is important that some form of effective customer sign-off is included in the process. The customer sign-off process provides vital data on customer satisfaction levels to enable the overall process to be fine-tuned. Moreover, forming a strong link with the customer is a critical part an effective business model for customised products. From the outset close communication with the customer is required to record their requirements/desires for the product and at the same time manage their expectations. Compromises often have to be made to ensure the product meets safety requirements can be manufactured effectively, as well as providing enhanced customer comfort levels. Another added complication is that some customised products may only demonstrate their true value in terms of increased comfort after several hours of use.

4. New Manufacturing Technologies

As demonstrated by Wimpenny et al. (2000) rapid prototyping techniques need to be more reliably deliver better accuracy, speed, and surface finish. Piller (2008) summarized the current limitations of ALM and identified the need to scale up production to enable mass manufacturing through rapid prototyping. (Piller, F. 2008). Three new processes were developed in the Custom-Fit project.

The team at TNO (Eindhoven, Netherlands) were responsible for managing the development of the High Viscosity Inkjet printing (HVIJ) process. This approach is based on continuous inkjet technology but the unit is configured to enable viscous materials to be deposited. A test rig was developed to enable a mandibular implant with a complex internal lattice structure to be produced using a UV curable bioresin (see Figure 3).

Figure 3 – The high viscosity inkjet printing test rig

The Metal Printing Process (MPP) was developed by the team at Sintef (Trondheim Norway). In this system a layer of metal powder is selectively deposited and then fused under high pressure within a heated chamber (see Figure 4). As opposed to laser/electron beam sintering the MPP process is effectively solid state sintering which allows very high integrity metal parts to be produced, including functional grading of several metals without appreciable alloying (Boivie 2006). In the Custom-Fit project MPP was developed for manufacturing the tibial implant.

Figure 4 - The MPP system

Figure 5 – SLP test rig at MTT Ltd

In the 3rd system developed, electrophotography (laser printing) is used deposit a precise patterned layer of a polymeric toner which is then fused using a radiant IR heat source to produce a solid thermoplastic object. In addition to relatively high production speeds the Plastic Printing Process, now known as Selective Laser Printing (SLP), has the potential to produce complex functionally graded materials using several thermoplastics in a single part. The SLP process was developed by DeMontfort University (Leicester, UK), MTT Technologies Ltd(Stone UK) and CTG GmbH (Alsdorf, Germany). A test rig was constructed to produce the seat, helmet and prosthesis demonstration parts in the Custom-Fit project (see Figure 5).

5. Case Studies

During the Custom-Fit project 6 case studies were undertaken to assess/demonstrate the potential of individually customised products;

- Motorcycle helmet
- Motorcycle seat
- Transfemoral prosthesis
- Tibial (knee) implant
- Mandibular implant
- Toy car seat

Although all of these cases studies successfully demonstrated different aspects of the benefits and challenges of introducing customised products, only the motorcycle helmet and mandibular implant will be described in detail in this paper.

5.1 Motorcycle Helmet: Bespoke motorcycle helmets have the potential to offer superior protection in terms of distributing crash forces over a larger area of the skull and also remaining in an ideal crash protection position on the head in the event of an accident. Figure 6 shows various stages through the virtual creation of a bespoke helmet insert comforted to the scan of the intended customer. **Step 1-** In this case the customer's head geometry was scanned using a body scanner (Human Solutions) and customer feedback was collected via a questionnaire (IBV). **Step 2-** That information was fed into DelCAM's Powershape platform to morph the standard helmet liner to conform to the customers head. The liner was further functionalized for ideal stiffness

and airways for cooling by adding an internal lattice structures using Marcam's VisCAM software(see Figures 6 & 7)..
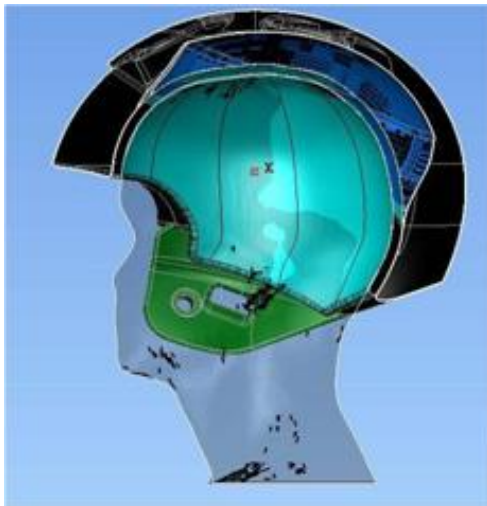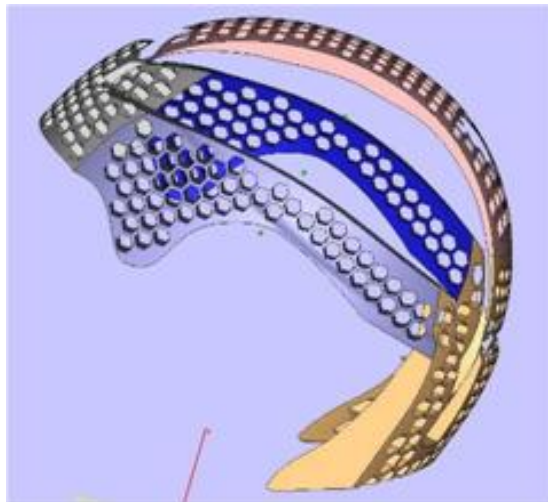

Figure 6 – morphing of standard liner　　　　**Figure 7 - customised liner**

Step 3- The morphed design is verified using FEA software from BPO to ensure that the design customisation is prevented from compromising safety (see Figure 8). **Step 4 -** The liner is produced using an existing rapid prototyping process, such as laser sintering, or by the new Selective Laser Printing process. The result is an affordable customised helmet insert which comforts to all certification standards
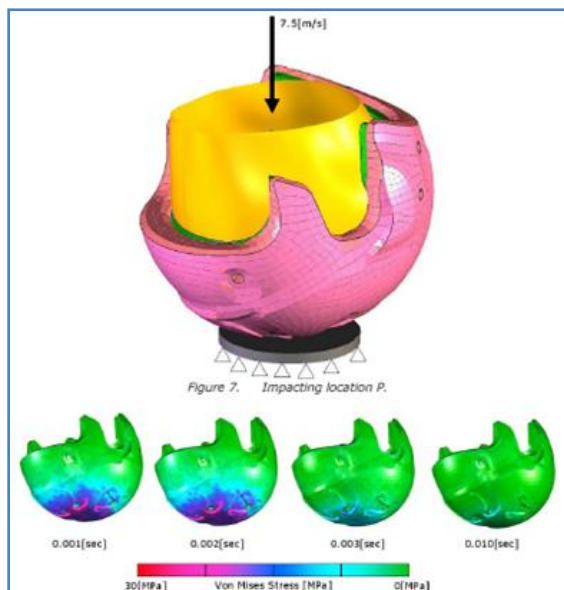

Figure 8 - virtual testing of customised liner

5.2 Mandibular Implant: Complex maxillofacial surgery maybe required to correct congenital defects, treat victims of trauma or remove advanced head/neck tumours. Unfortunately, the current conventional approach is to undertake hard tissue reconstruction using bone harvested

from a second surgical site. In addition to the associated surgical trauma and risk of infection it is almost impossible to obtain a perfect geometrical match for the required tissue. The use of customised metallic (typically titanium) implants, produced to the desired shape, is now becoming a more widely accepted surgical approach. However, many clinicians would prefer to utilise materials, such as bioceramics and polymers which can be formulated to resorb and be replaced with natural bone over time. In the Custom-Fit project the team at AZM (Maastricht, Netherlands) headed by Jules Poukens designed a customised implant to treat a mandibular defect. CT scan (dicom) data was loaded into the NSF system which, in addition to providing a way of recording patient information in a transferable file format, also tracks how the data is manipulated at each stage of the process to provide traceability for quality assurance.

The data was loaded into the maxillofacial implant design system, based on a combination of Mimics and 3Matic software, developed by the team at Materialise (Leuven, Belgium). The external geometry of the implant was designed and then InnerSpace software developed by TNO was used to transform the solid implant into a lattice with graded porosity to enable effective osseointegration of the implant. The data was then supplied to the HVIJ printing machine for printing of the bioresin implant. The new bioresin material developed in the Custom-Fit project is still undergoing the regulatory approval process and so the new implant could not be evaluated in a patient, however, accuracy and mechanical property trials were undertaken on the implant produced (see Figure 9).

Figure 9- bioresin implant inserted into model of mandible

6. Certification and Regulatory Issues

One of the major challenges with individually customised products is the need to ensure that products comply with the prevailing legislation with respect to performance. This is particularly important for products with inherent safety implications (in principle this could apply to any product). In the case of the custom-Fit case studies the helmet and prosthesis have important mechanical performance criteria which must be met. Regulatory issues are even more onerous for medical devices which will be implanted (for example the tibial and mandibular implants). The conventional approach to testing of products used for series production is impractical for on-off products, as this usually requires multiple tests to be conducted on products to failure. To enable customised products to be introduced requires a different approach based on either virtual testing of each customised product or testing of indicative products which span the range of customisation or limit the customisation to elements of the design which do not influence the safe performance of the product (this can lead to very inefficient designs).

In the Custom-Fit project, Dutch partner BPO investigated the restrictions imposed by the current statutory regulations and explored several alternative methodologies which could be applied to ensure the safe operation of individually customised products. Trials undertaken by

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BPO over many years, comparing the results of FEA predictions with the tests on real products, have shown that Computer Aided Verification (CAV) methods can provide an accurate and reliable prediction of the performance of products (Posthuma and Jansens 2007). Indeed in some cases the computer predictions can prove to be more effective as they can provide more incisive information than a simple pass or fail load test on real product. Unfortunately, although optimisation of designs based on the results of FEA is common practice, to replace physical testing with CAV will require extensive changes to product legislation.

Based the work undertaken in the Custom-Fit project BPO have proposed a radical new philosophy; Computer Aided Type Approval and Process Approval based on four approaches; Destining approach, Channels or bandwidth, approach, Iterative approach and Analytical approach (see Figure 10).
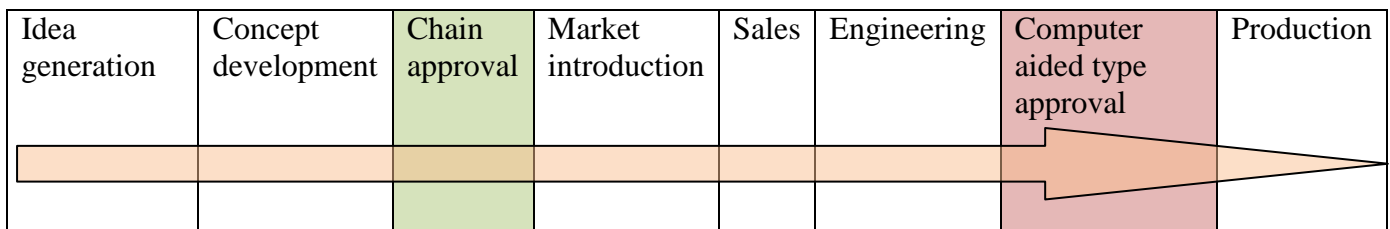
Idea generation	Concept development	Chain approval	Market introduction	Sales	Engineering	Computer aided type approval	Production

Figure 10- Product development process using Computer Aided Type Approval and Process Approval.

The destining and channels approach as used to gain type approval. In the **destining** approach the performance of a particular customised product is predicted and if it meets the performance criteria it will be produced. In the **channels** approach the limits of product customisation will be virtually tested and all products between these limits are assumed to be safe.

The iterative and analytical approaches are used to gain chain approval. Chain approval ensures safe products by using a robust process chain in which product performance validation is integrated. In the **iterative** approach a rapid succession of analysis is conducted and used to refine the design until satisfactory performance is achieved. In the **analytical** approach the design of the product is driven by design rules which define relationships between performance and product geometry through a KBE (Knowledge Based Engineering) route.

Of these approaches the analytical is probably the most elegant and in principle should be the most efficient, although significant investment is required to generate the design rules in the first place.

7. Discussion

Although significant progress has been made as a result of the Custom-Fit project, further work is still required to transform the dream of mass production of individually customised products to become a reality.

7.1 Market for customised products; although surveys conducted during the Custom-Fit project indicate a market for some individually customised products the information gathered is very limited in scope and tends to relate to niche products or customer groups. To obtain more meaningful (widely applicable) data is somewhat difficult since the benefit of customisation is not always clear to people who have not tried it.

7.2 Cost of collecting personal data; the custom-fit project highlighted some serious practical problems in the area of body scanning.
- Lack of 3D scanning equipment outside the medical world (except for a few pioneers like the footwear industry).
- Cost of employing someone to scan you.
- Cost of cleaning up scan data to provide a watertight file.
- Need for the NSF file (basically an XML based container).

7.3 Design customisation; despite the impressive results demonstrated to date, the design of customised products is still not fully automatic and represents a significant bottle neck and cost within the product development chain. Moreover, each product type requires its own design automation system which will be expensive to develop.

7.4 Design verification/certification; In addition to the cost and time required to verify the design of each customised product, extensive changes to product legislation will be required before the CAV approach can be widely adopted.

7.5 Manufacturing; Despite developments in Additive Manufacturing Technology the approach is still only viable for relatively small complex products, where a high quality surface finish is not essential. Moreover, we are currently hampered by the limited range and cost of materials available (particularly for plastic products).

7.6 Business integration; further work is urgently required to understand how customised products can be integrated within the current manufacturing and supply chain.

Finally if all of the technical challenges can be overcome care must be taken to avoid "over" customising products beyond the point of diminishing returns (Dewan *et al.* 2000).

References

Helms, M.M., Ahmadi, M., Jih, W.J.K., Ettkin, L.P. (2008) "Technologies in support of mass customization strategy: Exploring the linkages between e-commerce and knowledge management", *Computers in Industry*, Vol 59, pp. 351–363

Jones, J. And Wimpenny, D.I. (2008) "Digitally Customising Products for your Body, Bike, and World", presentation at the Time Compression Technologies 2008 Rapid

Manufacturing Conference, Coventry, UK.

Piller, F.T. (2008), "Making Mass Customization Work Strategies and Success Factors", presentation at the 3rd International Conference on Rapid Manufacturing, Loughborough, UK.

Tseng, M., Jiao, J. (1997) "Case-based evolutionary design for mass customization", *Computers & Industrial Engineering*, Volume 33, Issues 1-2, October 1997, pp. 319-323

Tseng, M., Jiao, J. (2001), "Mass customization", in Salvendy, G. (Eds), *Handbook of Industrial Engineering*, 3rd ed., Wiley, New York, pp.684-709.

Dewan, R., Jing, B., Seidmann, A. (2000) "Adoption of Internet-Based Product Customization and Pricing Strategies", *Journal of Management Information Systems*, Fall 2000, Volume 17, No. 2, pp. 9-28.

Zhang, S. (2009) "Recent progresses on real-time 3D shape measurement using digital fringe projection techniques", *Optics and Lasers in Engineering*, Article in Press, Corrected Proof. Available online: www.sciencedirect.com [Accessed 29 June 2009].

Wand, M., Berner, A., Bokeloh, M., Jenke, P., Fleck, A., Hoffmann, M., Maier, B., Staneker, D. Schilling, A., Seidel, H., (2008) "Processing and interactive editing of huge point clouds from 3D scanners", *Computers & Graphics*, Volume 32, pp. 204–220.

Stroud, I., Xirouchakis, P.C., (2000) "STL and extensions", *Advances in Engineering Software*, Volume 31, pp. 83–95.

Prieto-Diaz, R. (1993) "Status Report: Software Reusability," IEEE Software, Volume 10(3), pp. 61-66.

Piller, F. (2004) "Mass Customization: Reflections on the State of the Concept", *International Journal of Flexible Manufacturing System*, Volume 16, Number 4 / October.

Ong, M.H., Wagner, H., Tuck, C. and Hague, R. (2008) "Body-fitting customisation of motorcycle seats: an investigation of consumer requirements", *International Journal of Mass Customisation*, Volume 2, Numbers 3/4, pp.375–393.

Wimpenny D.I, Hayes, Goodship V., (2000), "Rapid Manufacturing - is it feasible?", *International Journal of CAD/CAM & Computer Graphics*, Volume 15, Numbers 2-3-4, pp 281-293.

Hague R., Campbell R.I. and Dickens, P.M., (2003), "Implications on Design of Rapid Manufacturing", *Journal of Mechanical Engineering Science*, pp 25-30.

Feenstra F., Holmer B., Tromans G., Moos N. and Mieritz B., (2003), "RP, RT, RM trends and developments / research survey" Proceedings from the 4th International Conference on RP and Virtual Prototyping, London.

Levy, G.N, Schindela, R. and Kruth, J.P. (2003) "Rapid Manufacturing and Rapid Tooling with Layer Manufacturing (LM) Technologies, State of the Art, and Future Perspectives", CIRP Annals - *Manufacturing Technology*, Volume 52, Issue 2, 2003, Pages 589-609

Boivie K., Metal Printing Process : A New Concept for Rapid Manufacturing, ESPOO, Sept 2006

Posthuma A., Jansens A., Certifying Mass Customised Products , technical paper downloaded from the RM platform (http://www.rm-platform.com/)