

Quality Management in Mass Production of Made-to-Measure Orthopaedic Footwear

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Presentation Guidelines

Thus far, major part of made-to-measure orthopaedic footwear was hand-made in small-scale orthopaedic footwear production shops, mostly family-owned. However, due to increasing costs of labour and growing deficit of healthcare system financing that resulted in financial pressures to orthopaedic footwear producers, most of them essentially shifted their operations into orthopaedic services business. Meanwhile, production has been transferred to specialized orthopaedic footwear production companies. For those, in turn saving their costs, it became fairly common to move their manufacturing operations to the regions with cheap labour. This way, the gap between the patient and producer grew wider, thus, in order to maintain the quality of order execution, there was the need for a significant improvement and increased formalization and unification of customized orthopaedic footwear design descriptions (biomechanical data).

Both in the past and nowadays, those design descriptions (biomechanical data) of made-to-measure orthopaedic footwear have been prepared by orthopaedic footwear technicians. One has to bear in mind that orthopaedic shoe cannot be considered merely as plain footwear, since it also serves the medical function of walking correction, therefore footwear technicians having undergone footwear designer and technologist training should also have some actual medical knowledge (biomechanical understanding of the human body movement). Furthermore, orthopaedic footwear design decisions are made for each patient individually, therefore it is very important for any orthopaedic footwear technician to make appropriate and technically finalized decisions regarding the ordered footwear so that manufacturer would be capable of adequately understanding them. It becomes particularly important when production is separated from patient care, whereat production of the last normally intended for correction of design errors early in the manufacturing process, becomes entirely impossible or economically unsubstantiated.

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Our practice has shown that design description methodologies of made-to-measure orthopaedic footwear differ not only across different countries, but also within one single country. Different

customers from the same country (it may be Germany, Benelux or Scandinavian states) not only differently measure the foot itself, but also select different reference points for presentation of measurements of individual footwear components. Hence, in order to standardize the collection of ordering data (biomechanical data) and thus to ensure an adequate understanding by manufacturer of the customer's data, we have developed an order configuration system for made-to-measure orthopaedic footwear, ShoeMetric®. It is a software system with the following principal functions:

1. To present a unified design description platform for made-to-measure orthopaedic footwear.
2. To provide assistance to the customer (orthopaedic footwear technician) filling the order by managing order description sequence, controlling data compatibility, offering multiple selections, and by providing on-line help.
3. To execute an examination of design decision entered by the customer by pointing out invalid specifications and validating those parameters, whose functional dependencies are possible to express via mathematical models.

Another aspect of quality management in mass production of made-to-measure orthopaedic footwear has to do with quality execution of design decisions submitted by the customer. The key production quality criteria are as follows:

1. Finished product should match the design description submitted by the customer.
2. The order should be executed by strictly meeting production deadlines that are set and agreed in advance.
3. Customer and its patient have to be satisfied with the execution of the order.

Despite that above mentioned quality criteria may seem obvious, they are not easily achieved in mass production of made-to-measure orthopaedic footwear due to the following particularities of customized production:

1. The order flow is variable, while production resources are limited. Therefore, in order to ensure the timely execution of orders and strict observance of production deadlines set and agreed in advance, manufacturer needs to have:
 - a. ERP (Enterprise Resource Planning) software system adopted for customized production that is capable of assisting the production manager to optimally manage

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production resources on one hand, and also of confirming order completion deadlines by taking into account available production resources and materials necessary for the order execution on the other.

- b. SCM (Supply Chain Management) system adopted for customized production. Traditionally, made-to-measure orthopaedic footwear production provides the possibility to the patient to choose from selected upper and sole materials, accessories and etc., therefore *ad hoc* supply chain management is a fairly complex task. On the other hand, supply chain management should be dynamic enough, so that investments in inventory could be controlled in line with incoming order flow by thus achieving required liquidity of inventory.
 - c. Qualified personnel with multiple qualifications able to work in several production stages depending on the need; extra workplaces that enable shifting employees around from one workplace to the other depending on the need.
 - d. Diversified order portfolio comprising both customized orders with short execution times and orders for standard orthopaedic footwear with relatively long order execution times. Existence of this portfolio enables to achieve considerable reduction of idle times. Idle times as such are inevitable in customized production with fixed execution deadlines.
2. Customized production character and fixed order execution deadlines. Based on our experience, we can state that the major factor putting timely order execution at risk today is inexact order descriptions received from customers. Producer loses significant amount of time and is forced to allocate additional time for examination and revision of order specifications. It is not uncommon to do so by drawing on production time. Delays are also caused by late supplies, especially in cases of non-anticipated distribution changes of materials selected by customer, as well as by nonconformity product removals. It is important to ensure timely identification of nonconformity product and its effective removal. Therefore, by seeking to ensure the timely execution of orders and strict observance of production deadlines set and agreed in advance, manufacturer needs to have:
- a. A unified orthopaedic footwear design description platform implemented in the form of order configuration (biomechanical data description) software system operating as an expert system.

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- b. PDM (Product Development Management) software system which is essential for complete real-time product development traceability. Real-time product development traceability is implemented by means of bar code scanning; upon completion of each manufacturing operation, the completing employee scans the order code, its working shift code and operation code. PDM system is the backbone production controlling system that enables monitoring of order execution times within the production schedule.
 - c. Possibility to manage and reschedule production resources as indicated in 1.1.
 - d. Timely identification (at earliest possible production stage) of nonconformity product.
 - e. Possibility to automate selected production steps and thus shorten the production cycle. Production process involves not only pure manufacturing, but also design steps. These design steps (such as designing the last or styling the model of a customized shoe) should not be understood as designing an entirely new product; they should rather be considered as *ad hoc* configuration of certain multipurpose prototype benchmark model based on individual needs of the patient, which is implemented by means of computer design. Our company uses ShoeMaster Orthopaedy® software system for computer modeling of lasts, ShoeMaster Premium® software system for customized shoe style modeling, which automatically runs the style specification, last shaping and leather cutting production centers. Using just ShoeMaster Premium® alone increases the productivity by as many as three times.
3. In order for the customer and its patient to be satisfied with the order execution, the product should be made strictly in line with design decisions submitted by orthopaedic footwear technician. It is important to ensure timely identification of deviations from stated requirements. Our company aims to achieve this by means of the following measures:
- a. Production technologies are fully formalized and documented. Every workplace is furnished with manuals on selected production steps; those manual requirements are mandatory. Every sub-product has its reference item, which in practice illustrates requirements set for the production of any given sub-product.

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- b. Inter-operational control of production steps (including also designing). Every employee, prior to performing assigned operation, controls the execution quality of the previous operation in accordance with production technology specifications.
 - c. Quality control of last, insole, upper and footwear assembly production steps is carried out by division managers.
 - d. The final quality control is carried out by the quality management group employee with qualifications of orthopaedic footwear engineer and designer-technologist.
 - e. If necessary, close communication with an orthopaedic footwear technician in the production process is maintained. Upon discovering mismatches between customer design requirements and actual data of the patient foot, the production is put on hold, the shoe-in-process is pictured with a digital camera or shot with a digital video camera and, in case the problem cannot be resolved locally, all material is sent to the customer to find the best solution.
 - f. Survey of customer and customer patient satisfaction is conducted by means of the questionnaire, seminars are held for orthopaedic footwear technicians employed by customers, whereat most common problems and their remedies are discussed as well as new technological solutions are presented.
 - g. Production errors are being recorded, including those design decision errors detected late in the production. Errors are traced both by employee and by operation in order to identify the weakest links and to ensure timely adoption of corrective measures.
 - h. Certain measures are taken to stimulate the responsibility of employees for their work results. The company invest considerable funds in development of corporate culture, team responsibilities. Furthermore, compensation of employees is tied both to their productivity and quality of operations performed, as noted above. The company runs yearly certifications of employees; depending on those certification results, employees receive qualification bonuses. Periodic training of employees is also carried out; the leading employees are paid extra salary for educating their less experienced colleagues, which provides incentives for effective knowledge transfer.
4. The quality management system of made-to-measure orthopaedic footwear production implemented in our company has been certified for EN ISO 9001-2000 standard. Certification has been awarded by Lloyd Register Quality Assurance Ltd. We believe that analogous

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system may be implemented in all manufacturing companies that position themselves as customized footwear producers. We do not think that there should be major differences, except for the fact that significant simplification of order configuration and preliminary order examination requirements should be achieved. After all, as mentioned above, orthopaedic shoe cannot be considered merely as plain footwear, as it also serves the medical function of walking correction. By ordering customized footwear for business or leisure, requirements for walking correction may be nonexistent at all, or they may be significantly less sophisticated.