Value, product delivery strategies and operational performance in the medical technology industry

Abstract

Healthcare systems face increasing demand and expectations due to globally aging populations and new technologies which will increase the demand for medical technology products. The 'value' of health technologies is based upon health technology assessment rather than customer perceptions. This research contributes to product delivery strategy and mass customization theory and contributes to practice by explaining how the proposed conceptual framework could enhance the value proposition of medical technology products, improving company performance and competitiveness. This paper used a 13-month, longitudinal, participative Action Research strategy to understand and improve the performance of a German medical technology company that manufactures prostheses with varying levels of customization. The conceptual framework was successfully applied in the case organization. It provided a structure for product segmentation which grouped products according to their value propositions which reflected different trade-offs in terms of health technology assessment (HTA). Appropriate delivery strategies were then determined for each group. This research demonstrated that product delivery strategies based upon postponement improved productivity and delivery performance, whilst reducing inventory and enhancing value.

Keywords: Product Delivery Strategies, Mass Customization, Medical Technology, Healthcare, Operations Strategy, Action Research, Value. (Patient Centred Care)

1 Introduction

For most products and services perceived value is "*the consumer's overall assessment of the utility of a product based upon the consumer's overall assessment of a product based upon perceptions of what is received and what is given*" (Zeithaml, 1988 p.14). However, what is received varies for different customers and value represents a trade-off between the benefits received compared to the costs incurred (Zeithaml, 1988). Healthcare, products are mostly commissioned by governments or insurance companies rather than individual patients. The concept of 'value' in healthcare is usually determined objectively by Health Technology Assessment that evaluates improvements in the quality of life, morbidity or mortality profiles; or cost reductions for stakeholders (Peiffer *et al.*, 2019). Patients with improved outcomes in response to treatments receive greater value than those who do not (Hu *et al.*, 2005). Therefore, healthcare providers stratify patients in accordance with predicted responses to determine the appropriate treatment. Thus, the notion of 'value' in healthcare is different than for most products and services as it based on clinical evidence rather than customer perceptions.

In 2020, the European medical technology market was valued at roughly €140bn which represented 27.6% of the worldwide market, the second largest in the world, after the United States (MedTech Europe, 2020). Medical devices may make significant improvements to the

quality of life of patients. The medical technology supply chain has the following parts: producers (product manufacturers); purchasers (Group Purchasing Organizations (GPOs); wholesalers/distributors; and health care providers (hospital systems and integrated delivery networks (IDNs)) (Burns, 2002). The sector has experienced rapid growth in recent years due to demographic changes, such as aging global populations and wealthier emerging markets that demand better healthcare and products (Holtzman, 2012). Germany has an international-oriented and successful medical technology industry where there are over 1,200 medical technology manufacturers (95% are SMEs employing less than 250 people). Two thirds of revenue is produced outside its domestic market (BMBF, 2015). In 2018, the total turnover of German medical technology firms was €30.3bn (BVMed, 2019). Studies conducted by AT Kearney (2017) and Ebel *et al.* (2013) showed that half of medical technology and pharmaceutical companies had deficiencies such as an absence of a formulated strategy, a lack of efficient planning and coordination processes or unreliable sales forecasts. This paper presents an Action Research study that addressed these issues. It was conducted in a German medical device company representative of this industry and employing approximately 380 staff.

The medical technology industry produces products that may be either standardized or personalised to meet the needs of a specific patient and/or the commissioner of healthcare. Although there are many issues common with other manufacturing sectors, the supply of medical devices is linked to complex clinical pathways that connect diagnosis, treatment, and rehabilitation. The concept of personalization focuses on the interaction of service professionals with customers to identify needs (De Blok *et al.*, 2013). The patient would typically attend several clinics, which would include scans that provide the necessary information to select a standard medical technology or to manufacture a customized item. In both cases the patient receives a personalised service (García-Villarreal, 2018). Standardized medical devices such as artificial joints may be supplied in standard sizes that are delivered in batches, whereas personalised devices are manufactured on an individual basis to meet a bespoke specification provided by the clinician (García-Villarreal, 2018).

Mass-customization strategies have been adopted by many organizations as a way to tailor their products/services to a large customer base in order to increase value (Jost and Süsser, 2020). Lampel and Mintzberg (1996) considered a continuum of strategies from pure standardization through to pure customization, where customized products are produced to satisfy individual specifications (Ramdas, 2003). Such products are often produced on an engineer-to-order basis, where the design of the product is an important part of the contract (Hicks *et al.*, 2000a). Mass customization allows companies to produce customized products in high volumes at low cost by using flexible processes. It is *"a production strategy focused on the broad provision of personalized products and services … mostly through modularized product/service design, flexible processes, and integration between supply chain members"* (Fogliatto *et al.*, 2012 p.15). More recently, other researchers have considered mass customization, including Cattani *et al.* (2010) who proposed "spackling", an approach for balancing efficient standardized production and flexible customized manufacturing; and Lawson *et al.* (2018) who considered multi-modal build-to-forecast (BTF) / build-to-order

(BTO) systems in an automotive context.

There has been a move to extend such customization approaches to incorporate co-design with a customer to enhance the emotional connection with a product or service (Oliveira *et al.*, 2019). Many mass-customization studies have focused on what a customer will pay, what they will purchase, and if they will choose mass-customization if it is offered – however, research is lacking on how co-design can enhance value (Turner *et al.*, 2020). In healthcare the issue of co-design is not usually an option but a requirement. The product is co-designed using the professional judgement of healthcare professionals and the medical device companies rather than with patients. Co-design is therefore a key enabler of the service. Previous studies have not addressed the use of product delivery strategies and mass-customization where co-design is a requirement as opposed to an operational strategy. Secondly, in other sectors, mass-customization and co-design results in uniqueness for the end customer, which may increase the cost of the product/service. However, the end customer is willing to pay extra due to the enhanced value received (Oliveira *et al.*, 2019). However, in healthcare the patient may not get the option to decide whether they receive a standard or customized product as the decision is made by the commissioner (Jost and Süsser, 2020). Medical technology companies must demonstrate value to both the patient and the commissioner. In most other sectors, the focus is primarily on the customer.

This paper addresses how alternative products with different value propositions can be produced more competitively in the healthcare sector where patients receive a personalised service. In other sectors (e.g., telecommunications, defence systems, infrastructural products) organizations can choose to compete on cost (by producing large volumes of a standardized product); on quality (by offering more customization to the product/service) or by uniqueness (by co-producing the product/service with the customer). The medical technology sector must encompass all three. How these companies configure their processes in order to enhance the value propositions of the finished products can impact on the quality of life of the patient and the competitiveness of the company.

This research considers the nature of ‘value’ of medical products, which is very different from most manufactured consumer products; it addresses a gap in the literature relating to medical technology companies’ application of product delivery strategies and mass customization through the following research question: How can product delivery and mass-customization theory be developed to enhance the value proposition of medical technology products to improve performance and competitiveness? To answer this research question an Action Research strategy was adopted and implemented in a typical German medical technology company.

This paper is organised as follows: Section 2 presents a review of the literature. Section 3 presents the conceptual framework that forms the contribution of this work. Section 4 outlines the methodology, followed by a description of the Case Company in Section 5. Section 6 considers the research process, results and analysis. This is followed by the discussion and conclusions and possible future work. The appendices provide details of the Action Research project.

2 Literature review

The literature review is presented as three sections: value creation; healthcare systems, commissioning, and value in healthcare; and product delivery strategies, mass-customization and postponement.

2.1 Value creation

Early work on value engineering by Miles (1961) considered four types of 'value': *use value*, the qualities and properties which are required for use; *esteem value*, which relates to the features, properties or attractiveness perceived by the owner; *cost value*, the sum of costs incurred producing the product; and *exchange value*, the properties or qualities which enable it to be exchanged for something else (Lindgreen and Wynstra, 2005). The construct 'value' has been used and measured by a range of disciplines including accounting and finance (e.g. book value, market value, replacement value etc.), purchasing (e.g. use value, cost value), economics (e.g. exchange value, use value, cost value) and marketing (e.g. economic value to the customer, and value in use) (Payne and Holt, 1999; Lindgreen and Wynstra, 2005).

Groth *et al.* (1996) considered that although value takes different forms, the types can be classified as being either economic or non-economic value. Economic value can be measured in monetary terms, whereas non-economic value relates to the additional non-economic utility realized by one or more people. Traditionally, from an accounting and finance perspective, company performance was measured in terms of accounting profits and the associated ratios, such as return on equity and return on assets. The Economic Value Added (EVA) Model was first applied by Stern Stewart & Co in the 1990s. In contrast to traditional accounting profit metrics it takes into account the cost of capital (Kyriazis and Anastassis, 2007). *"In its simplest form, EVA is the after-tax cash net operating profit less a charge for the capital employed to produce those profits"* (Stern *et al.*, 1996, p.236). EVA increases shareholder value by increasing the return on assets tied up in the business. It encourages investment when the returns are greater than the cost of new capital. It also encourages disinvestment from activities that have substandard returns (Stern *et al.*, 1996).

Creating and delivering superior customer value for individual customers will increase the value of an organization, which quantifies the worth of an organization to its owners (Woodruff, 1997). A company can only create economic value if it satisfies customer need with transactions generating gross returns when goods and services are paid for (Groth *et al.*, 1996). *"A company enjoys competitive advantage if it offers customers the most attractive perceived value to cost ratio"* (Groth *et al.*, 1996, p.26). Value and price are independent; the perceived value is the perceived benefit of the product minus the product price and the cost of ownership. The value of the same product varies for different customers depending upon their perceived benefit (Lindgreen *et al.*, 2012).

A "product" is the total package of benefits a customer receives when buying a product or service. It includes the functional utility of the goods, the service provided, the seller's brand and reputation and assurance that the product will be delivered where it is needed and in the

correct quantities. Customers may also benefit from technical and personal relationships that form part of the 'package of benefits' (Corey, 1975, p. 122). A *"buyer's perception of value represent a trade-off between the quality or benefits they perceive in the product relative to the sacrifice they perceive by paying the price"* (Monroe, 1990, p.46). *"Customer value is a customer's perceived preference for and evaluation of those product attributes, attribute performances, and consequences arising from use that facilitate (or block) achieving the customer's goals and purposes in use situations"* (Woodruff, 1997, p.142). The augmented product concept recognises that different products levels (generic product, expected product, augmented product and potential product) can provide customers with additional value (Levitt, 1980). The generic product is the basic product (steel, wheat, insurance etc.). The expected product represents a customer's minimal purchase conditions possibly including delivery (location, timing, flexibility, volume); terms (quantities, prices, discounts, payment terms); advice and support, as well as ideas and suggestions for use. The generic product can only be sold when customers' wider expectations are met. An augmented product goes beyond what customers expect either in terms of product features or associated services. The potential product is everything that might be done to attract and hold customers (Levitt, 1980).

Bowman and Ambrosini (2000) argued that a potential customer must establish how the product or service will satisfy their needs, considering that any decisions made will be in advance of consuming a product, or receiving a service, and therefore, determines the use value (as perceived by a customer) and exchange value (the price). Similarly, Browning (2003) viewed value as incorporating two aspects: *intrinsic value*, which is determined by how well the attributes of the product or service satisfies customer needs; and *relative value*, where the value also depends on competing or alternative products or services. However, customers may perceive value differently at the time of purchase than during or after use. Product attributes are considered in purchasing decisions, but consequences are more important when evaluating use (Woodruff, 1997).

Vargo and Lusch (2004, p.2) commented that *"marketing has moved from a goods-dominated view, in which tangible output and discrete transactions were central, to a service-dominated view, in which intangibility, exchange processes, and relationships are central"*. The focus should be on the value-creating system where various actors such as suppliers, customers and business partners coproduce value. In addition, it is important to clarify what kind of value is created, for whom it is created and what resources and mechanisms are used to create the value (Saarijärvi *et al.*, 2013).

Collaborative buyer-supplier relationships provide a source of competitive advantage. Firms have consolidated their supply bases by changing from having adversarial relationships with many suppliers to developing long-term relationships with key suppliers (Ulaga and Eggert, 2006). Relationship value is a measure of cocreated outputs, where the nature of interaction between the supplier and customer is critical to the creation of value (Lindgreen *et al.*, 2012). From a value perspective suppliers can differentiate themselves from the competition by contributing to customer value by either providing benefits or reducing costs (Ulaga and Eggert, 2006). Palmatier (2008) proposed a model of customer value that took into account relationship

quality (trust, commitment, reciprocity, norms and exchange efficiency), contact density (the number of relational ties) and contact authority (the decision-making capability of the relational contacts.

Ulaga and Eggert (2006) identified that in addition to the core product suppliers create value through service support, personal interactions, reducing acquisition and operational costs, providing know-how, reducing time to market, and by allowing the customer to outsource activities. The commitment to relationship building and maintenance and the distribution of surplus value will vary according to the importance of the relationship to each party and the balance of power in the relationship (Lindgreen *et al.*, 2012). Based upon the resource-based view (Barney, 1991), Sirmon *et al.* (2007) identified that managers create value in three ways: i) structuring activities that includes decision-making processes for acquiring, accumulating and divesting resources; ii) integrating resources through stabilizing, enrichment and pioneering processes; and leveraging activities which involves mobilizing, coordinating and deploying resources (Lindgreen *et al.*, 2012).

2.2 Healthcare systems, commissioning, and value in healthcare

Healthcare systems are complex. Mossialos *et al.* (2017) provided detailed information on worldwide health care systems, their funding arrangements and structure. Some countries, such as the US, Germany and the Netherlands have insurance-based systems, whereas healthcare is funded by the tax payer in the UK, Sweden and New Zealand (Woodin, 2006). Whilst individual patients may purchase some healthcare services privately, the majority of healthcare services are commissioned or contracted by an organization such as an insurance company or national health service, rather than by an individual patient. This is a different situation to consumer goods and services which are purchased by the customer.

A reimbursement code is necessary to allow commissioners to pay for a medical technology, thus it is critical to the competitiveness of a medical technology (Ginty *et al.*, 2010). Before medical technologies can be made available manufacturers need to prove their capability to produce products at regulated levels of quality, safety and consistency. This is major barrier to market entry for new products and providers.

In healthcare, services are intangible and involve simultaneous production and consumption (Osborne and Strokosch, 2013). Patients are not customers at the end of a production process, rather they experience pathways of care (Smith *et al.*, 2020). Young and McClean (2008) identified that there are three critical dimensions to healthcare value: *operational value*, relating to the effectiveness and efficiency of service delivery; *experiential value,* based upon patient perceptions of the care environment and interactions with staff; and *clinical value,* arising from effective care that achieves the desired clinical outcome (Darzi, 2008). This can be argued to represent a value cycle where a number of exchanges occur between at least two stakeholders, who initially co-create value, before separately obtaining the benefits of the value created (Le Ber and Branzei, 2010). The different stakeholders (commissioners, patients, clinical and non-clinical staff, managers, and regulators) may place different emphasis on these dimensions of value (Smith *et al.*, 2020).

From the commissioners' perspective 'value for money' is concerned with cost effectiveness, which relates to the transformation of costs into outcomes through a number of stages: i) the purchase of inputs e.g. labour, capital and drugs; ii) these are used to provide activities such as surgical procedures and diagnostic tests; iii) to produce outputs such as episodes of care; leading to iv) outcomes, including improvements in the length and quality of life and patient experience (Smith, 2009). The measurement of outcomes has several dimensions: *health gain*, measured in terms of quality adjusted life-years, is the key indicator or the success of an intervention; *patient experience* that takes into account issues such as waiting time, privacy, empowerment, autonomy and choice; *inequalities* which is concerned with variations in the access to healthcare; *socio-economic outcomes,* which may include increased productivity as well as reduced care costs (Smith, 2009). As a consequence, *"…value may be created and captured instantly (e.g. a vaccine takes a short time to administer); in other cases, value creation and capture can take much longer (e.g. building a value chain for reliably administering a vaccination program may take years)*" (Le Ber and Branzei, 2010 p.603).

Health Technology Assessment (HTA), used by commissioners of healthcare to establish intrinsic and relative value, "*is a method of evidence synthesis that considers evidence regarding clinical effectiveness, safety cost-effectiveness and, when broadly applied, includes social, ethical and legal aspects of the use of health technologies. The precise balance of these inputs depends upon the purpose of each individual HTA. A major use of HTA is in informing reimbursement and coverage decisions, in which the HTAs should include benefit-harm assessment and economic evaluation"* (Luce *et al.*, 2010 p.271). *"In this context, 'technology' is defined broadly to include drugs, devices, procedures, and systems of organization of health care, although in practice, it is commonly applied more narrowly*" (Luce *et al.*, 2010 p.258).

Customized products must provide additional value to justify any additional cost relative to standardized mass-produced products. Medical technology companies, therefore, need to provide a strong value proposition to get their innovations assigned a reimbursement code (Ginty *et al.*, 2010). Value may be based upon: improvements in health outcomes at a cost deemed 'good value' based upon improvements in the quality of life, mortality or morbidity profile; or reductions in cost for one or more stakeholders (Peiffer *et al.*, 2019), as evaluated by Health Technology Assessment (Luce *et al.*, 2010).

2.3 Product delivery strategies, mass-customization and postponement

Marucheck and McClelland (1986) considered manufacturing to be a continuum extending from pure engineer-to-order (ETO) at one end, to pure make-to-stock (MTS) at the other. The choice of whether to manufacture on a make-to-stock or make-to-order basis was considered to be a strategic decision that is based on a number of factors (Marucheck and McClelland, 1986). First, the make-to-stock configuration allows the delivery lead-time to be minimised as products are delivered ex-stock. However, holding finished goods stocks increases the requirement for short-term capital and can have negative impact on cash flow and liquidity (Christopher and Gattorna, 2005). Make-to-stock production is associated with the production of products with standard configurations. The make-to-order (MTO) approach eliminates the requirement to

hold finished goods stocks, but the customer is then exposed to the cumulative lead-time. This strategy can be employed with either standardized or customized products. It also minimises the risk of obsolescence or write-down. Companies that produce products on an engineer-to-order basis do not have the strategic option to manufacture to stock as the product is not fully specified until the design is complete (Hicks *et al.*, 2000b).

Some literature refers to the terms configuration-to-order (CTO), build-to-order (BTO) and build-to-forecast (BTF). ETO products are examples of CTO that includes decisions relating to product design, procurement and suppliers, production, distribution and IT/systems (Gunasekaran and Ngai, 2009). Where MTO includes the manufacturing of components as well as their subsequent assembly, BTO mostly relates to assembly operations where the components are outsourced (Gunasekaran and Ngai, 2009). BTF is a strategy that can make the delivery lead-time much shorter than the manufacturing lead-time. The manufacturing orders are released before customer orders are received. When customer orders arrivals are matched to units that are in progress. If an order arrives during the early stages of production variant changes can still be made. Alternatively variants may need to be swapped on a previously completed product, which incurs additional costs (Raturi *et al.*, 1990). Thus, BTO is similar to assemble-to-order and BTF is a variant of MTS which allows both early and late customization (Meredith and Akinc, 2007). Lawson *et al.* (2018) considered multi-modal BTF/BTO systems in an automotive context. BTO adopts a mass customization approach that is embedded within a stable high volume production system. With BTO customers are exposed to the manufacturing lead-time, thus they are making trade-offs between extended delivery lead-time against their preferred product configuration. The BTO approach was found to be more profitable than BTF. Further, the company can use BTO to manage excess demand by encouraging customers to select and wait for customized products. Multi-modal systems have become flexible allowing modifications up to the start of production. The aim is to have a responsive system that meets customer demand in terms of product configuration and lead-times.

The traditional manufacturing strategy for producing a mix of MTS and MTO products would be to have a focused approach (Skinner 1974). Cattani *et al.* (2010) considered using offshore facilities for producing standardized MTS products at minimum cost and flexible local facilities for producing MTO customised products. Soman *et al.* (2004) noted that whilst the literature had mainly considered pure MTS or MTO strategies, combined MTS/MTO systems were increasingly common. Cattani *et al.* (2010) considered alternative strategies where the demand for standardized items was used to smooth the demand for customized products. MTO products were produced first, with MTS production occurring when there was available capacity. They compared a pure ‘spackling’ (filler) strategy, where a single, flexible strategy was used to meet the demand for both MTS and MTO products with ‘layered spackling’, which combined an efficient facility for producing standardized products with a flexible facility for customised products with the traditional focused factory approach. They concluded that total costs may be lower if some standardized products are manufactured in more expensive flexible facilities rather than producing all standardized products in an efficient low-cost facility.

Mass customization is a production strategy that aims to provide personalized products and

services through flexible processes, modular designs, postponement/delayed product differentiation and integrated supply chains (Fogliatto *et al.*, 2012). The mass customization process can add value by: increasing the fit between the product and customer's preferences; minimizing the design effort associated with the customer order; and the customer's satisfaction gained from configuring the product (Franke *et al.*, 2010). Lampel and Mintzberg (1996) considered that customization could be positioned on a continuum spanning five alternative strategies (Figure 1): i) *pure standardization* in which products are designed to meet the requirements of a broad group of customers. Identical products are then produced in high volume, achieving economies of scale which reduces cost. The products are then distributed to the market using a common process; ii) *segmented standardization* that develops a range of standard products with relatively minor design variations to provide a limited range of features to meet the requirements of different subgroups; iii) *customized standardization*, which allows customers to choose from a standard range of options. In this case, the components are standardized, but the assembly processes are customized to meet the specifications of individual customers; iv) *tailored customization* in which products with fundamentally common designs are modified to meet the requirements of specific customers; and v) *pure customization* where products are designed and manufactured to meet individual customer requirements. This spectrum spans from fully standardized mass production through to fully customized bespoke production (Lampel and Mintzberg, 1996).

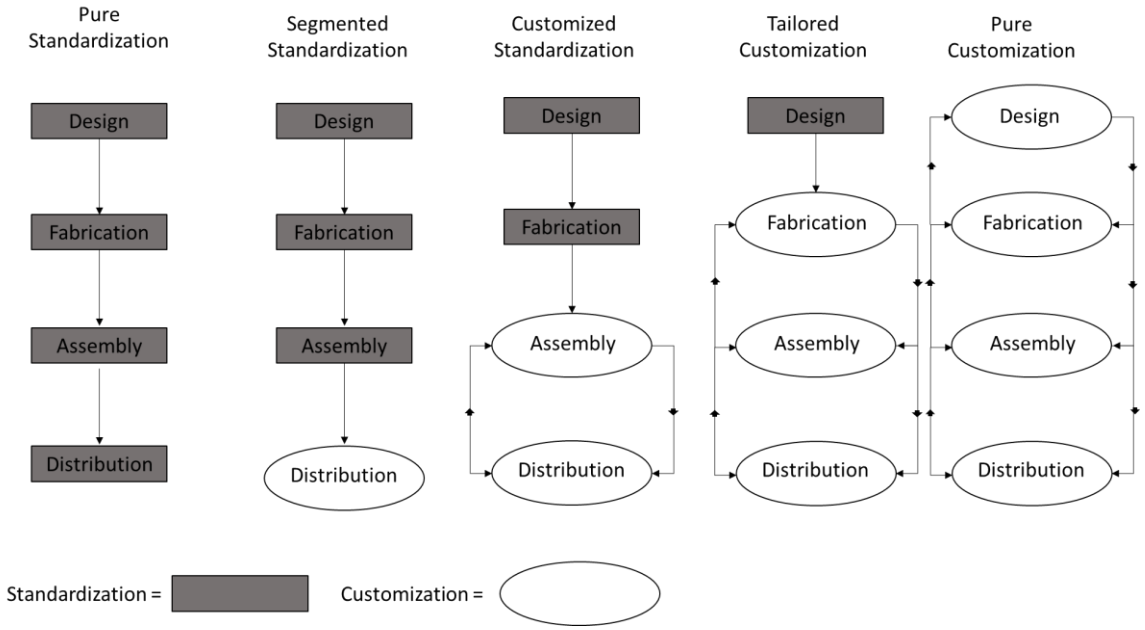


Figure 1 A continuum of strategies (Lampel and Mintzberg, 1996)

Mass customization seeks to achieve low costs and high variety to meet the needs of individual customers (Pine, 1993). Gilmore and Pine (1997) proposed four approaches to customization based upon two dimensions: product (no change / change); and representation (no change/change). The four resulting quadrants were: i) *adaptive customization*, where a standardized product can be customized by users, for example installing applications on a

computer (no change/no change)*;* ii) *cosmetic customization* presents a standard product in alternative ways to different customers, for example through the use of different packaging (no change / change)*;* iii) *transparent customization* is where products are customized to providers with unique products or services, without the customer being aware of the customization (change / no change)*;* and iv) *collaborative customization* where there is a dialogue with individual customers to define their needs in order to produce a customized product (change / change). 'Adaptive customizers' and 'cosmetic customizers' are examples of assemble-to-order (ATO) strategies. With adaptive customization the customer is responsible for assembly, whereas with cosmetic customization the product is produced on an ATO basis by the manufacturer (Meredith and Akinc, 2007 p.624). From the firm's point of view, the significant factors that influence the success of mass customization strategies include the ability to handle uncertainties and complexities in demand and supply chain activities (Blecker and Abdelkafi, 2006; Liu *et al.*, 2010; Shirwaiker *et al.*, 2013). Moreover, differences in customers' expertise, and their willingness and ability to partake in mass customization activities have significant influence on the success of mass customization strategies (Duray, 2002; Buffington and McCubbrey, 2011).

Mass customization capability relates to *"the ability to reliably offer a high volume of different product options in a relatively large market that demands customization without substantial trade-offs in cost, delivery and quality"* (Zhang *et al.*, 2014 p.146). Mass customization capability has four main aspects (Qi *et al.*, 2020): *high volume customization* relates to aggregation of individual customer demand into large batches with common parts; *customization cost efficiency*, providing products at a similar cost to mass production; *customization responsiveness*, minimizing the lead-time; and *customization quality*, which is the ability to guarantee the quality of all customized products (Zhang *et al.*, 2015). Mass customization capability can help build close relationships with customers to obtain knowledge about their requirements and market changes (Qi *et al.*, 2020).

Olhager (2003 p.319) defined the order penetration point (OPP), also known as the customer order decoupling point, as "*the stage in a value chain where a specific product is linked to a customer order*". Different positions of the OPP lead to alternative product delivery strategies such as make-to-stock, assemble-to-order or make-to-order (Olhager, 2003). Postponement can be used as a strategy to facilitate mass customisation by moving the OPP, which can improve agility and be a cost-effective strategy for enhancing product customization (Jost and Süsser, 2020). The operations postponed may be at the product design, purchasing/ordering, manufacturing or distribution stages of the supply chain (Yang *et al.*, 2004). Postponement decisions are mainly based upon known demand rather than forecasts. The delay associated with postponement increases the amount of information available, which helps reduce risk and uncertainty.

Postponement can take various forms: *place postponement* maintains inventory in centralized stores and delays the movement to a final location until an order is received; *time postponement* delays the movement of inventory; *pull postponement* makes the order decoupling point earlier so that product differentiation can be delayed; *form postponement*

delays finalising the configuration of the finished product within the manufacturing system until user demand is known (Yang *et al.*, 2004; MacCarthy and Brabazon, 2006). Alternatively postponement may be classified as: *logistics postponement* (combinations of place, time, pull and form postponement); *production postponement* keeping undifferentiated work-in-progress that can used to flexibly produce products that satisfy demand; *purchasing postponement* which delays the purchase of raw materials until demand is known; and finally *product development postponement*, where there is no inventory and the product is engineered-to-order (Yang *et al.*, 2007). This is illustrated in Figure 2 which shows that the different postponement strategies relate to alternative positions of the order decoupling point.

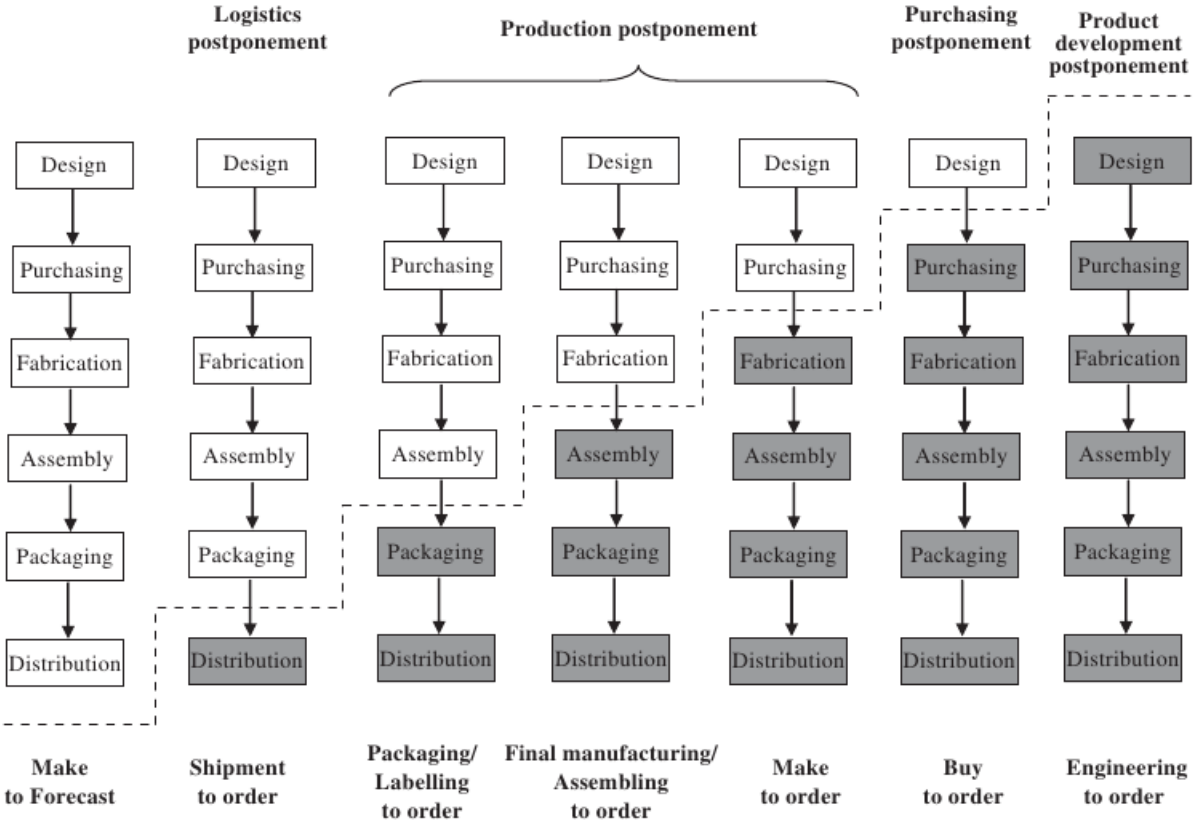


Figure 2 Postponement strategies (Yang *et al.*, 2007)

3 Conceptual framework

Figure 3 presents a conceptual model which integrates the theories discussed in the literature review. There are five product delivery strategies that arise due to changes in the customer order decoupling point / order penetration point (Olhager, 2003) that determines the configuration of processes, the level of customization, the delivery lead time and the value proposition of the resultant products as well as the level of co-design and relational value. There is a continuum that spans from product delivery strategy I (standardized products made speculatively to stock

based upon forecasts) at one extreme to product delivery strategy V (highly customized products that are designed and manufactured to meet individual customer requirements) at the other extreme. With standardized products the value proposition concentrates on minimizing cost; appropriate manufacturing strategies could include high volume production that achieves economies of scale. With highly customized products the value proposition is based upon augmentation of the product and relational value that arises from the co-design of the product to meet the individual customer requirements in terms of the product specification (McGovern and Hicks, 2006), through life use and end of use. It is also necessary to understand individual customer's priorities in terms of value criteria. Whilst a manufacturer may adopt one of these extremes, if the product that is offered needs some customization, the intermediate strategies II-IV can be adopted.

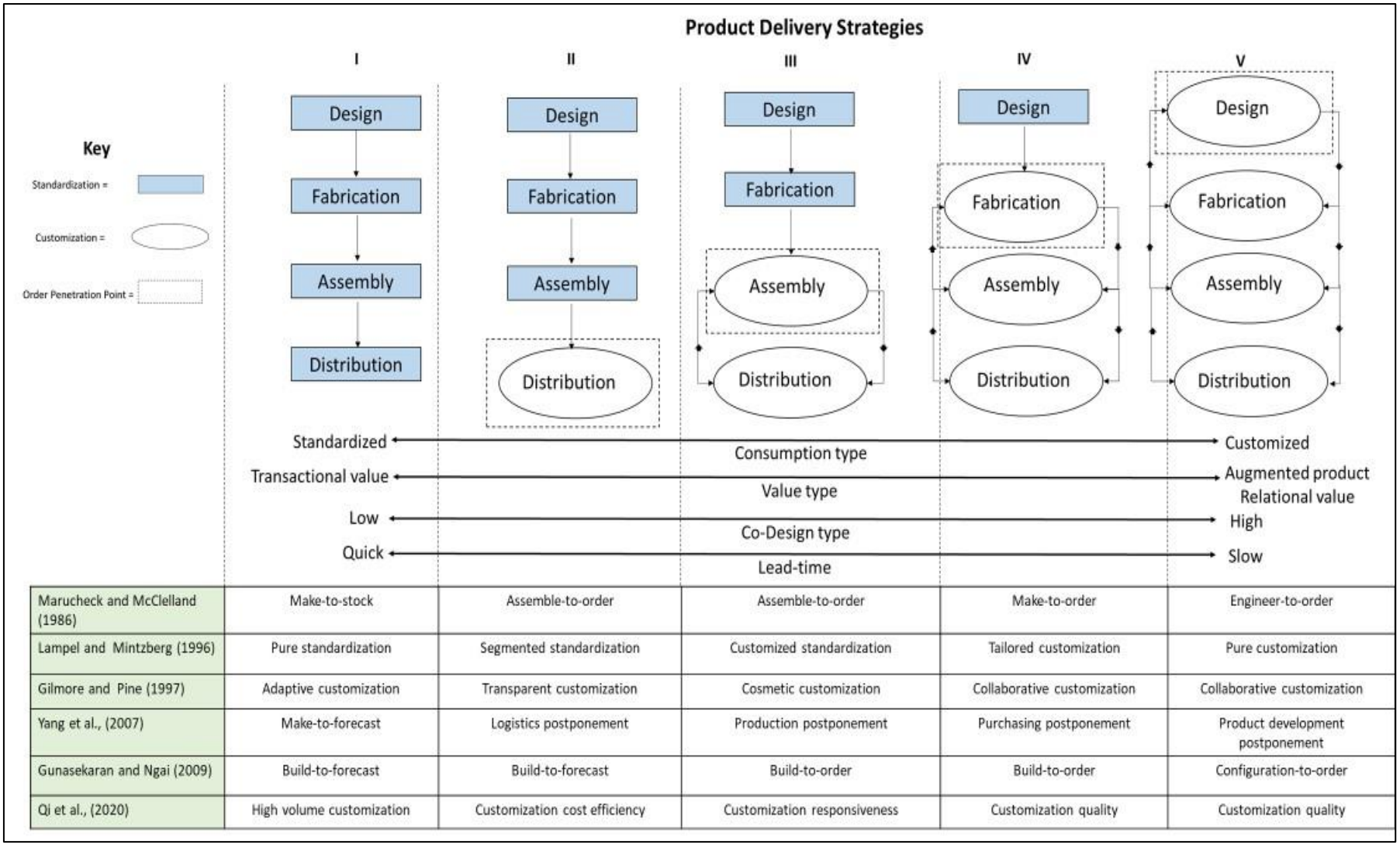
Delivery strategy I produces standardized products on a make-to-stock basis (Marucheck and McClelland, 1986) referred to as pure standardization by Lampel and Mintzberg (1996). This strategy minimizes cost and the delivery lead-time as products are supplied from stock. However, the strategy can also be coupled with postponed customization at various points in the value chain. With adaptive customization standardized products can be tailored by customer after purchase (Gilmore and Pine, 1997). With build-to-forecast (Gunasekaran and Ngai, 2009) standard products are associated with customers order arrival allowing either early or late customization. High volume customization (Qi *et al.*, 2020) aggregates customer demand so that large batches of product can be produced in a cost efficient manner.

At the other extreme, product delivery strategy V produces customized products on an engineer-to-order (Marucheck and McClelland, 1986) or pure customization basis (Lampel and Mintzberg, 1996). This is relatively high-cost, and the delivery lead-time can be long as it equals the cumulative lead-time, which include all design and product fulfilment processes. In terms of the Gilmore and Pine (1997) typology, this is referred to as 'collaborative customization' where there is a dialogue with individual customers to identify and satisfy their needs. This configuration was termed 'product development postponement' by Yang *et al.* (2007) and fits within the 'configuration-to-order' category (Gunasekaran and Ngai, 2009). Customization capability comprises the ability to guarantee the quality of customization and to maintain close relationships with customers (Qi *et al.*, 2020).

Product delivery strategies I-V determines the level and nature of customization. Product delivery strategies II-IV represent intermediate points of the continuum. These five product delivery strategies are not exclusive and can be used in combination by organizations seeking to meet the requirements of different market segments. Multi-modal strategies can lead to the best system wide outcomes (Lawson *et al.*, 2018) for example by balancing demand and capacity for efficient standardized production and flexible customized manufacturing (Cattani *et al.*, 2010).

Previous work has adopted each of these theories and used them within different manufacturing or service contexts. No previous work has combined them within a single conceptual model that includes the value propositions that each product delivery strategy incorporates. The conceptual model allows organisations to identify if the best product delivery

strategy is being utilised and where more relational value or transactional value is appropriate. By applying strategies based on the conceptual framework, this research identified how medical technology companies can simultaneously improve the value proposition, performance and competitiveness for different market segments.



Marucheck and McClelland (1986)	Make-to-stock	Assemble-to-order	Assemble-to-order	Make-to-order	Engineer-to-order
Lampel and Mintzberg (1996)	Pure standardization	Segmented standardization	Customized standardization	Tailored customization	Pure customization
Gilmore and Pine (1997)	Adaptive customization	Transparent customization	Cosmetic customization	Collaborative customization	Collaborative customization
Yang et al., (2007)	Make-to-forecast	Logistics postponement	Production postponement	Purchasing postponement	Product development postponement
Gunasekaran and Ngai (2009)	Build-to-forecast	Build-to-forecast	Build-to-order	Build-to-order	Configuration-to-order
Qi et al., (2020)	High volume customization	Customization cost efficiency	Customization responsiveness	Customization quality	Customization quality

Figure 3 Product Delivery Strategies conceptual framework

4 Methodology

This research adopted an Action Research (AR) approach to evaluate the development of product delivery strategies in a typical medical technology company that designs, manufactures and supplies protheses and the associated instruments. The aim of the intervention was to help the Company understand its challenging market environment and how it could improve its competitiveness by developing and applying new product delivery strategies to increase resource utilisation and the value propositions for different market segments. The research strategy closely followed established Action Research practice in operations management (Hales and Chakravorty, 2006; Salerno, 2009; Schmidberger *et al.*, 2009; Formentini and Romano, 2011; Dey *et al.*, 2015; Gylling *et al.*, 2015; Clegg *et al.*, 2017).

Action research (Lewin, 1946; Susman and Evered, 1978; Clegg *et al.*, 2017) provides a rich setting for theory testing and theory building (Eisenhardt and Graebner, 2007; Yin, 2009) and can fulfil the purposes of case study research, including 'discovery', 'description', 'mapping', and 'relationship building' (Näslund *et al.*, 2010). Action Research emphasises practical relevance and deals with real-world organizational and managerial issues (Näslund, 2002), where research informs practice, and practice informs theory (Avison *et al.*, 1999).

The research strategy used what Oliva (2019) described as a '*mode 2*' intervention, as the research sought to understand how theory, applied through Action Research impacted the organization's operations. The research used a single embedded design (Gylling *et al.*, 2015) that followed Susman and Evered's (1978, p. 588) Action Research model, comprising: *Diagnosing* - identifying or defining a problem; *Action Planning* - considering alternative courses of action for solving a problem; *Action Taking* - selecting a course of action; *Evaluating* - studying the consequences of an action; and *Specifying Learning* - identifying general findings (Appendix B provides the details of how AR was applied in this study). The quality criteria adopted in this research followed Zuber-Skerrit and Fletcher (2007), which built on the earlier work of Bradbury and Reason (2001). This established six requirements' researchers should address in order to improve the quality and validity of an Action Research study. Table 1 below sets out how these requirements were satisfied.

Zuber-Skerritt and Fletcher's (2007) requirements	This Study
Practice-oriented	The research developed and tested theory to meet the requirements of the Case Company.
Participative	Twenty individuals participated throughout the research (Table 3).
Inclusive to the community/organization or fellow human beings in the wider world	Workshops were conducted to design new processes based on theoretical recommendations and with the cooperation of key stakeholders of the Case company. An inclusive approach was taken with extensive communication and participation of stakeholders.
Using multiple perspectives of	Data collection included: interviews, workshops, participative

knowing for triangulation	observation, and quantitative operational data (Figure 4 below).
Contributing something new to knowledge in theory and practice	An integrated conceptual framework was developed.
Explicit about assumptions	The research made few assumptions. The objectives and outcome measures were agreed by participants.
Reflective, critical, self-critical, and ethical.	There was reflection within and between each action research cycle. Stage 5 specifically identified learning.

Table 1 Improving the Quality of Action Research

A team-based approach was adopted to avoid any researchers' bias (Eisenhardt and Graebner, 2007). This helped to increase the rigour of the data collected in terms of reliability and helped achieve investigator triangulation (Näslund *et al.*, 2010). The Researchers' roles were established before the research commenced, as recommended by Näslund *et al.* (2010). Appendix A presents the different roles of the Researchers. The distinction between Action Research and Consulting is not always clear and becomes a main point of criticism of studies of this kind. A reflective, cyclical approach was therefore used that avoided turning AR into consulting (Baskerville and Wood-Harper, 1996). Gill (1986) outlined the main differences between Action Research, consulting and "basic" research along the stages of a project (see Table 2).

Stages	**Action Research**	**Consultancy**	**"Basic" Research**
Entry	Client or researcher presents a problem. Mutually agreed goals.	Client presents problems and defines goals.	Researcher presents problems and defines goals.
Contracting	Mutual control.	Consultant controls client.	Researcher controls as expert. Keeps client happy.
Diagnosis	Joint diagnosis. Client data/ researchers' concepts.	Consultant diagnosis. Often minimal. Sells package.	Researcher carries out expert diagnosis. Client provides data.
Action	Feedback. Dissonance. Joint action plan. Client action with support. Published.	Consultant prescribes action. Not published.	Report often designed to impress client with how much the researcher has learned /published.
Evaluation	New problems emerge. Recycles. Generalizations emerge.	Rarely undertaken by neutrals.	Rarely undertaken.
Withdrawal	Client self-support.	Client dependent.	Client dependent.

Table 2: Differences between Action Research, consultancy, and 'basic' research (Gill, 1986, p.103).

In contrast with roles associated with consulting or 'basic' research, Action Research requires what Gill (1986) calls 'mutual control', meaning that both the case organization and the Researchers must have control over the approach, the research direction and diagnosis based upon the case organization's data and the Researchers' concepts. Action took place after each workshop, with the workshops being a platform to agree on changes and direction and to monitor the joint action plan. The evaluation of results was a continuous process that was based on the monitoring of key performance indicators (KPIs) and feedback given by the project team members. The withdrawal stage was closed once that evidence of the organization's assimilation of the new processes and ways of working existed.

The range of stakeholders involved in the project included managers, staff members, suppliers and a customer. Table 3 shows the role of participants, the rationale for participation, their role during the study and the stage(s) where they were involved.

Code	Role	Rationale for participation in study					Role during the study			Stage of involvement				
		Policy maker	Decision maker	Information source	Project team	Project management	Interviewee	Workshop participant	Project coordination	Stage 1: Diagnosing	Stage 2: Action Planning	Stage 3: Action Taking	Stage 4: Evaluating	Stage 5: Specifying Learning
I1	Managing director	X	X				X	X		X				X
I2	Factory manager	X	X				X	X		X				X
I3	Vice president sales	X	X				X	X		X				X
I4	Vice president operations	X	X				X	X		X				X
I5	Master scheduling manager					X			X	X	X	X	X	X
I6	Vice president supply chain	X	X				X	X		X				X
I7	Vice president finance	X	X				X	X		X				X
I8	Logistics manager			X	X		X	X		X	X	X	X	X
I9	Vice president marketing	X	X				X			X				X
I10	Production manager			X	X		X	X		X	X	X	X	X
I11	Master scheduling manager			X	X		X	X			X	X	X	X
I12	Sales department manager			X	X			X			X	X	X	X
I13	Sales representative			X	X			X			X	X	X	X
I14	Launch management representative			X	X			X			X	X	X	
I15	Marketing manager			X	X			X			X	X	X	
I16	Production supervisor			X				X				X	X	
I17	Material procurement representative			X	X		X	X		X	X	X	X	X
I18	Supply chain manager			X	X		X	X		X	X	X	X	X

I19	Customer A			X				X				X	X	
I20	Supplier C			X				X				X	X	
I21	Action researchers					X		X	X	X	X	X	X	X

Table 3: Study participants, their roles and involvement

Figure 4 shows the stages of the research, which are described in detail in Appendix B and strictly follow (Oliva, 2019): *diagnosing, action planning, action taking, evaluating, specifying learning.*

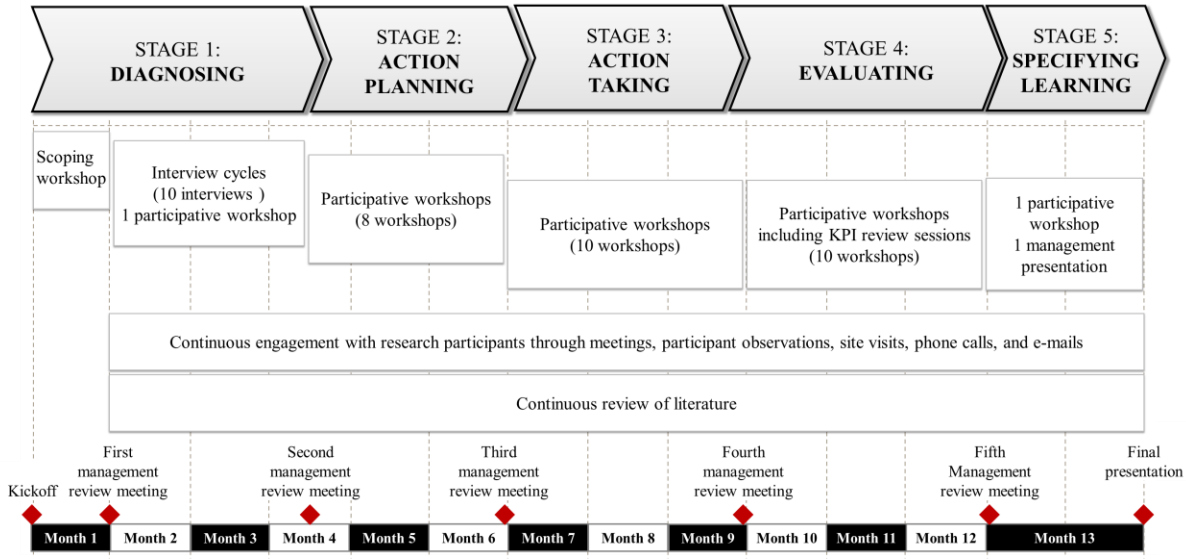


Figure 4 Stages of the research

5 The Case Company as an exemplar of its industry

The case company is based in Germany and employs 380 employees worldwide. It produces devices for hip and knee arthroplasty (keyhole surgery) and spinal surgery. Over the last thirty years, the Company has developed a sales presence in over 20 countries. Its main capabilities are the development, production, and sales of implants for primary and revision endoprostheses including all the surgical instruments required for hip, knee, and spine arthroplasty. Patient health and safety are the top priorities. Arthroplasty presents several challenges to surgeons and designers, as materials for implants must be resistant to corrosion, non-hazardous, bio-compatible and long lasting. The Company's main priorities are the safety of implants and technological development. Designers collaborate extensively with physicians and mechanical engineers. Patents, exclusive licenses and tacit knowledge were used to protect the Company's competitive advantage.

The product portfolio consisted of over 5,000 types of implants and 4,000 instruments. Hip endoprostheses and instruments accounted for 60% of the total sales volume in 2019; knee endoprostheses and instruments 25%; and spine endoprostheses 15%. Europe accounted for 70% of turnover, with international sales of 30%. The Company's key stakeholders are

customers (hospitals, clinics, wholesalers, and group purchasing organizations) and raw material and component suppliers. Most manufacturing is undertaken in-house to ensure quality and compliance with regulations and to secure the company's core know-how. The Company has centralized cost centres responsible for quality inspection, laser drilling, sterilisation, and packaging and decentralized cost centres responsible for the mechanical processing of parts (turning, milling, drilling etc.).

The Company produces both standardized and 'patient-sized' prosthesis; Zeller *et al.* (2017) used the term 'patient-sized' to refer to medical technology products individually made for patients following an engineer-to-order approach, involving co-design with healthcare professionals. At the start of the research, the Company manufactured both pure customized (ETO) and tailored customized (MTO) products using the same resources. The Company supplies the prosthetics in a surgical kit that includes the instruments required for the operation, which are loaned. The service, which includes just-in-time (JIT) delivery and collection of the used instruments, according to an agreed schedule, significantly reduces workload for hospitals and clinics, thus creating added value for these organizations. In consequence the Company needs to manage the logistics associated with the return and resupply of loaned items. Surgical kits comprising standard prosthesis and all the instruments required for the operation are assembled-to-order and supplied to physicians and recycled after use. The service element of supply is also customized for these products.

The Company's value proposition went beyond being a provider of medical devices as it took over the logistics functions of hospitals and clinics, including the return of used instruments. The Company had problems with: on-time delivery performance; backlogs; high levels of inventory for finished goods; longer lead times than their competitors; and low-capacity utilization. The Company required clear production and product delivery strategies to meet the requirements of different market segments and also appropriate KPIs to assist with evidence-based decision making.

6 Research process, results and analysis

It was agreed with the organization that the researchers would spend two days every two weeks on-site during the project. At the end of each meeting the participants reflected on the progress made. Data were collected through semi-structured interviews, workshops, plant tours, observations, and documentary analysis. Data gathered in workshops were summarized in minutes of meetings, which were distributed to workshops participants for review. Data collected from interviews (see Stage 1: Diagnosing in Figure 4) were analysed by deductive and inductive coding and clustering (see Appendix C). In order to achieve triangulation, the research included multiple research methods (methodological triangulation), multiple sources of data (data triangulation), and a team-based approach to conduct the project (investigator triangulation) (Näslund *et al.*, 2010).

6.1 The development and application of key performance indicators (KPIs)

The research team worked closely with top management to define common goals for the organization (Figure 4, Stage 1: Diagnosing). The Company had engaged in process improvement using Lean approaches since 2013 and had sought to optimise logistics processes, reduce cycles times and minimise packaging waste. There had been several initiatives that aimed to reduce inventories, such as the use of Kanban to manage the supply of consumables and components. However, there was a lack of trust in suppliers that could potentially become competitors. This led to poor information sharing, which undermined the application of 'pull' systems. Fluctuations in the price of commodities also led to large orders and safety stock. The key factors that undermined operational performance were: 1) there was erratic customer demand from the European and Asian markets. Sales were not consolidated to smooth production; 2) the Sales Department tended to order finished goods 'just in case'; 3) the Production Department focused on machine utilization at the expense of other performance indicators, leading to an imbalanced manufacturing strategy that produced high stock levels; and 4) although staff engagement was considered to be high, management commented that the overwhelming majority of employees did not passionately pursue the organization's mission, with *"people doing a good job, but still waiting for management to tell them what to do, instead of stepping up and doing the right thing" (I10, 2015)*.

To address these challenges, KPIs were established to measure operational performance (see Table 4, Column A). The analysis revealed a total inventory of €24.4m with finished goods €13.6m (56%). The Days of Inventory Outstanding (DIO) was 112 days (inventory turnover 2.14). The on-time and in-full delivery rate (OTIF) was 83%, despite the 'just-in-case' inventory, which caused rush orders. Forecast accuracy was not measured, with sales not being held accountable for the finished goods inventory, which was the responsibility of the Master Scheduling Department. Following the analysis of the status quo, operational targets for the Action Research project were defined by the Company's management as shown in Table 4, Column B.

Organization's KPIs	**A**	**B**	**C**	**D**
	Baseline	**Target for Month 12**	**Actual Month 9**	**Actual Month 12**
Total inventory in Euros [€]	24.4 €M	17.0 €M (-30%)	21.2 €M (-13%)	16.5 €M (-32%)
Inventory turnover [times per year]	2.14/year	3.06/year (+43%)	2.44/year (+14%)	3.15/year (+47%)
Days of Inventory Outstanding (DIO) [days]	112 days	78 days (-30%)	98 days (-13%)	76 days (-32%)

On-Time-In-Full delivery [%]	83% OTIF	95% OTIF (+14%)	88% OTIF (+06%)	98% OTIF (+18%)
Backorders [%]	17%	5% (-70%)	12% (-29%)	2% (-88%)
Capacity utilization [%] (machine park)	79%	85% (+07%)	78% (-01%)	84% (+06%)
Average lead-time (all orders) [days]	20 days	14 (-30%)	17 (-13%)	13 (-32%)
Sales forecast accuracy [%]	Not measured	Not declared target	68% (32% MAPE)	86% (14% MAPE)

Table 4 Organizational KPIs Improvement during the project

6.2 Business Processes and Value Streams

Interviews and workshops were conducted with the main process stakeholders (Managing Director, Factory, Sales, Operations, Master Scheduling, Supply Chain, Finance, Logistics, Marketing, and Production Managers) to map the business processes (see Figure 4, Stage 1: Diagnosing). The Researchers employed Value Stream Mapping (VSM) (Rother and Shook, 2003) and Business Process Modelling and Notation (BPMN) (Kocbek *et al.*, 2015) and then made an abstraction of these as shown in Figure 5 (product delivery strategy I) and Figure 6 (product delivery strategy V).

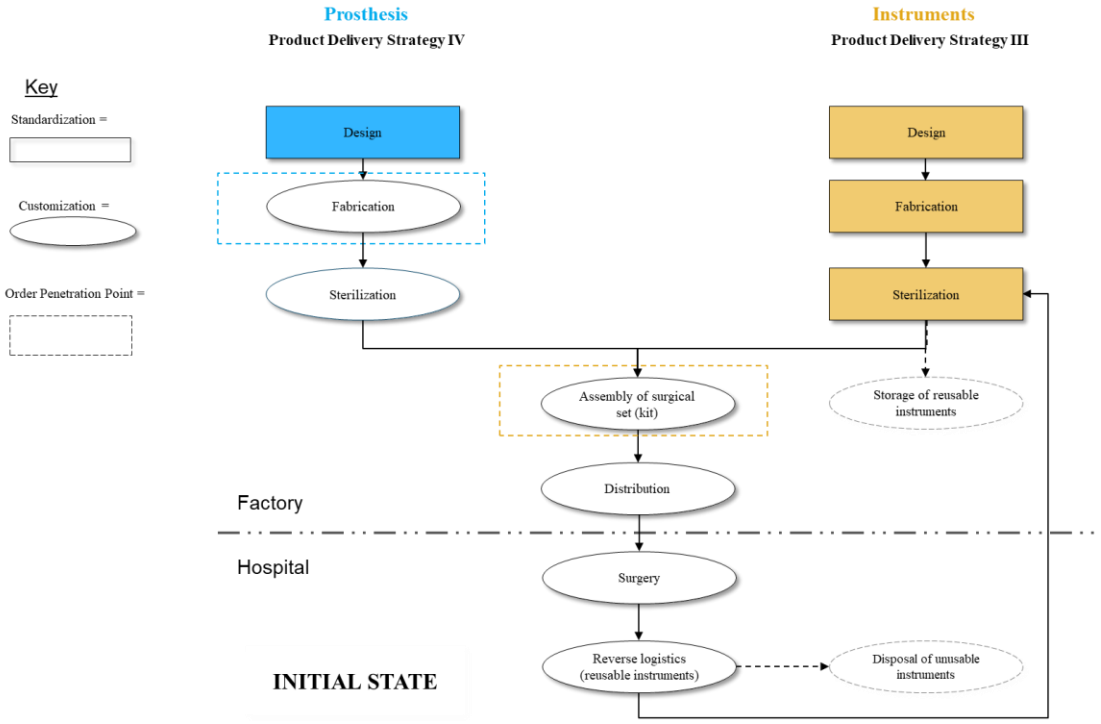


Figure 5 Initial state of processes and decoupling points for tailored prostheses (MTO) and instruments

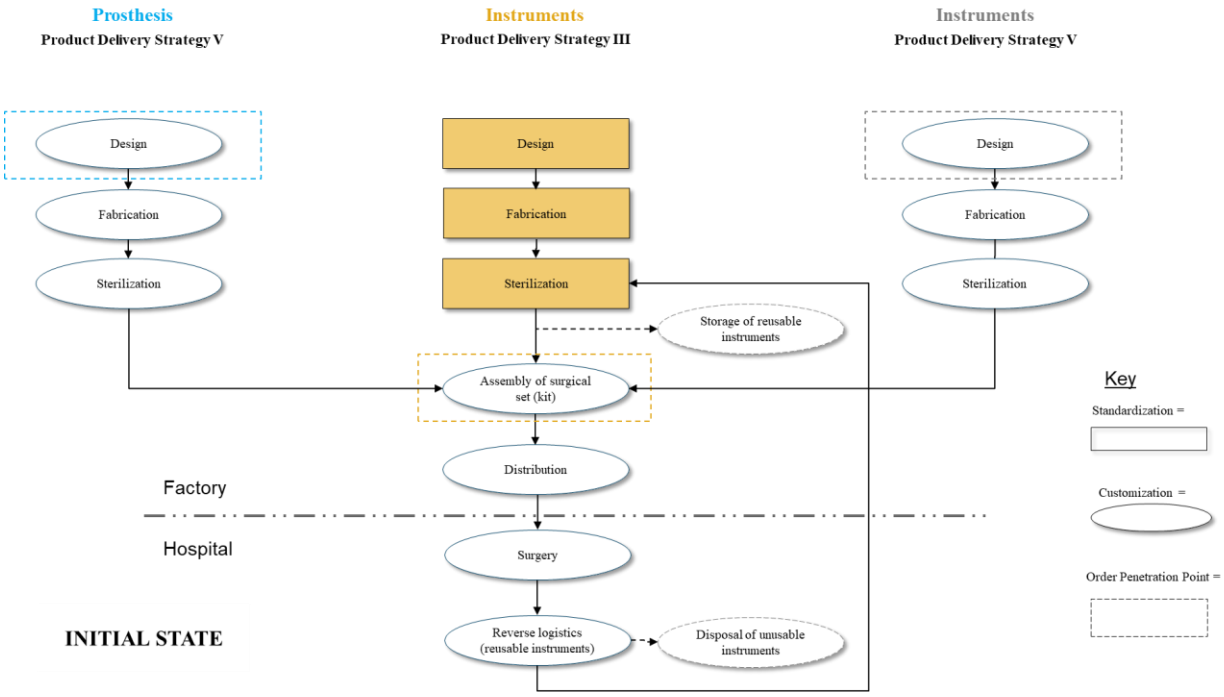


Figure 6 Initial state of processes and decoupling points for pure customized prostheses (ETO) and instruments

Customers required short lead-times and on-time delivery, with orders being shipped from small finished goods inventories available in the plant and distribution warehouses. Prosthesis production demand was both 'patient-sized' (ETO) (40%) and standardized (60%). The delivery lead-time for tailored products was 5 days and 30 days for products supplied on a 'patient-sized' basis. The Company received demand information from customers with a planning horizon of one year through their Industrial and Financial System (IFS). The ERP system automatically generated a production plan, which was checked for consistency by the Master Scheduling Department. Marketing and Sales Department then placed call-offs in the ERP system (AS/400), without any adjustments to smooth production.

Interviewees I2 and I10 argued that there was no integration between customers and suppliers, but rather a process where production tried to meet incoming orders put in the system. I3 and I6 claimed that demand plans were available for the organization in the IFS platform. Additionally, the organization was mainly focused on selling as much as possible and it sourced raw material in large batches without taking capacity, transportation, and warehouse space constraints into account.

> *"Production plans initiated in the ERP system were released, but the effectiveness of the plans was not measured at all. Productivity was regarded as the most important parameter [for the business] and Production Department Managers were more concerned with keeping this high as a priority. There was no effort to measure objectively if production had met the plan, but rather if machines were occupied at a reasonable rate…In the end, the only thing that our factory manager is interested in, is our productivity". (I10, 2015).*

Additionally, consolidation meetings between those responsible for demand planning and supply planning were unsuccessful due to a lack of management input.

> *"Maybe you should drop by when we have our consolidation meetings. They happen once a month. But it is hard to make a decision in those meetings when the boss is not around. Normally, we use that meeting to let others know what is wrong with this or that, but there is only a handful of people who try to be proactive and make sure that things work out in the end" (I8, 2015).*

The Shipping Department responded to customer order information provided by the Master Scheduling Department, which produced a rough production plan. Planning of volumes and mix was made at a product family level. Manufacturing, on the other hand, was driven by work orders generated automatically by the ERP system (AS/400) with some minor adjustments made by the staff from the Master Scheduling Department. The ERP system produced these work orders based on direct customer demand and system-generated forecasts intended to replenish inventory levels. The direct customer of the Manufacturing Department was the warehouse for semi-finished goods. Planning of work orders was made at an item number level according to the push principle. Some consideration of production constraints occurred at resource level (machine or machine groups).

The Factory Manager was responsible for day-to-day decisions:

> *"I guess the hardest part of [the Factory Manager's] job is making decisions for the*

complete organization. He decides which customers are going to get products on time and which customers are not; if we need new personnel in the Maintenance Department to make sure that our machine park is running; or if we need to buy new shelves to expand the capacities in our warehouse" (I8, 2015).

6.3 Analysis of product demand and initial improvements

Representatives of all relevant stakeholders were involved in the analysis and design of the processes and agreed on a schedule for the implementation of changes. Participants evaluated whether the products were produced using a tailored customized (MTO, product delivery strategy IV) or pure customization (ETO, product delivery strategy V) approach. Appropriate positions for the order penetration points in the value chain were identified for products and instruments. Factors such as demand variability and volume were also considered.

A systematic analysis of product demand and volumes based on Lean principles was conducted to understand the characteristics of the product families. Volume analysis techniques included ABC/XYZ; where ABC prioritizes mix according to volume, and XYZ categorizes products according to stability of demand (Scholz-Reiter *et al.*, 2012). The analysis identified that the OPP for 80% of tailored prostheses could be postponed to the 'assembly' of the operation set, as the demand for these products was almost without variation i.e. the kits could be supplied on a customized standardized (ATO) basis (product delivery strategy III). This meant that the process for tailored customization (product delivery strategy IV) could only be applied for 20% of tailored prostheses. The implementation of the postponement approach required the installation of three Kanban replenishment loops (downstream to upstream): one at the distribution centre, one right after final quality inspection, and one right after the turning work centre. Moreover, a further Kanban loop between the case organization and its main supplier of titanium was also designed.

In terms of standardized instruments, the proposed system design reduced the number of variants to: (1) to decrease complexity in the production of instruments; and (2) to significantly reduce stock levels for returned used instruments. It was not necessary to change the OPP for pure customized (ETO) prosthesis (product delivery strategy V). However, improvements in the way patient information was translated into a design and how work orders were transferred to manufacturing were identified. In the Design Department new standards were defined together with a streamlined process. In manufacturing, machines were assigned to separate cells according to the mode of supply (customized standardization, tailored customized or pure customization). The cell for pure customization/ETO (product delivery strategy V) also accommodated the production of prototypes. This avoided contention for resources and conflict between the different product families.

In order to reduce the range of instruments the Design Department moved towards using standard rather than bespoke instruments. This reduced costs and workload, whilst making stock control easier and improving stock availability, which reduced lead-times and improved delivery reliability. Finally to improve planning and to increase the accountability of the Sales Department, forecast accuracy (measured using mean absolute percentage error) was

introduced as an additional KPI, together with procedures to gather the necessary data to enable monthly reporting.

6.4 Re-configuring product delivery strategies

The redesign of the case company's product delivery strategies required the implementation of appropriate organizational, technological, and cultural changes. A series of participative workshops including a customer and a supplier were undertaken (see Table 3 and Figure 4, Stage 2: Action Planning). The outcome of each workshop was to agree changes, which were subsequently implemented in accordance with a joint action plan. Results were evaluated continuously based on the monitoring of the KPIs (see Section 6.1) and feedback was obtained from project members. This approach continued until there was sufficient evidence that the new processes and ways of working had been fully assimilated and were sustainable. The main challenges were to ensure a sustainable change, to convince employees at all organizational levels of the necessity of the new processes, and to reinforce compliance and accountability for the new processes. The product delivery strategies were introduced via participative workshops, in which comprehensive training programmes were delivered, accompanied by coaching and monitoring based on the project's KPIs (Figure 4, Stage 3: Action Taking). The focused factory approach identified the product split between customized standardization (ATO) (high runners/product delivery strategy III), tailored customization (MTO) (low runners/product delivery strategy IV), and pure customized/prototypes (ETO) (one-offs/product delivery strategy V). The Company then segmented its production capacities to support the production of these groups. By adopting the strategy of *form postponement* (Yang *et al.*, 2004; MacCarthy and Brabazon, 2006) for customized standard prosthesis (product delivery strategy III), a Kanban loop at manufacturing level was established to manage manufacturing orders and to delay the configuration of the finished products (surgical sets comprising prosthesis and instruments) until user demand was communicated to the Case Company. This reduced the order processing lead-time and increased the responsiveness of the organization for high-runner products (product delivery strategy III).

To distinguish between these product groups manufacturing cells were introduced, which required changes to the layout. One of the most important changes was the shift from centralized production areas to decentralized production areas (e.g., quality inspection, laser drilling, final inspection). This approach meant that high runner products (product delivery strategy III) had dedicated machines for their production and were therefore freed from costly changeovers. The machines in the high runners' cell could easily achieve a utilization of over 85%. When changeovers were required, the setup times were reduced by using the Single Minute Exchange of Dies (SMED) method. The Company installed decentralized Kanban loops for the production of high runners. Production at each process step was triggered when a minimum stock level was reached. This changed the system from 'push' to 'pull' production.

The new concept foresaw that machines for low runners (for tailored prosthesis, product delivery strategy IV) and patient sized/prototypes (product delivery strategy V) should not be expected to have high-capacity utilization; the objective was to finish shift-sized work packages

('buckets'), as planned by the Master Scheduling Department. The processes for both low runners (tailored prosthesis and 'patient-sized' products) were controlled according to a 'pull' logic. The Master Scheduling Department determined lot sizes and sequences of work orders for each work centre that minimized the number of changeovers during shifts.

Following recommendations from the literature (Lapide, 2005; Grimson and Pyke, 2007; Thomé *et al.*, 2012), the Sales Department was made accountable for finished goods stock and revising forecasts, the quality of which was measured using mean absolute percentage error (MAPE). Regular sales and operations planning meetings were held between the employees estimating demand and those responsible for supply. In terms of reverse logistics, the Company's strategy of reducing complexity by streamlining its product portfolio proved highly successful, as the replenishment of instruments became more organised with fewer missing parts. This reduced instrument stock levels and improved logistical processes.

6.5 Improvements

Table 4 summarises the effects of the improvement activities on overall performance, as evaluated during Stage 4: Evaluating and Stage 5: Specifying Learning (Figure 4). As illustrated in Column D, the organization's inventory turnover rate increased significantly (+47%) while the DIO and inventory levels decreased by 32%. This was a consequence of stock levels for tailored prosthesis being more balanced after shifting the OPP to the 'assembly' of surgical sets for high-runner products (customized standard prosthesis). In terms of the Qi *et al.* (2020) classification this achieved *customization responsiveness;* the design and manufacturing process for pure customized prostheses became more streamlined, achieving *customization quality*. The system was better able to distribute workload to dedicated resources. Based on an analysis of demand, the number of types of instruments was reduced. These changes improved on-time-in-full delivery by 18% and reduced lead-time by 32%. This reduced back orders for both prosthesis and instruments by 88%. The implementation of manufacturing cells according to the mode of customization increased the overall machine utilization rate by 6% without compromising On-Time-Delivery. The monitoring of forecast accuracy led to more reliable demand forecasts which reduced work-in-progress and finished goods inventory.

The conceptual framework identified the possibility of moving from high cost product delivery strategy V to more standardized solutions, such as product delivery strategies III and IV. It provided a basis for redesigning processes that were suitable for product delivery strategies III (ATO), IV (MTO) and V (ETO), each addressing different market segments and customer needs (in this case, not only the patient's interests and concerns, but also those of clinicians or even insurance companies). Figure 7 shows the redesigned processes for Group 1: high-runners for customized prostheses (ATO/product delivery strategy III) and standard instruments (product delivery strategy I), which was a new category that arose from the analysis. The categorization (product groups 1 to 3) provided a framework for implementing Cellular Manufacturing where each cell operated according to relevant performance criteria. The high-volume cell for manufacturing standardized prostheses (product delivery strategy III) was set up to operate at high utilization (that is, high batch sizes with minimal changeovers),

whereas the cell for pure customized products and prototypes (product delivery strategy V) targeted improved delivery performance (requiring an additional planning effort in the master scheduling department to define appropriate time buckets, batch sizes, and changeovers). Further, appropriate techniques for inventory management and setup time reduction could be applied as appropriate. The Company chose a focused factory approach to multi-modal manufacturing instead of 'spackling' to minimise changeovers and so that dedicated machinery could be used for the high runners (product delivery strategy III), which accounted for the majority of demand.

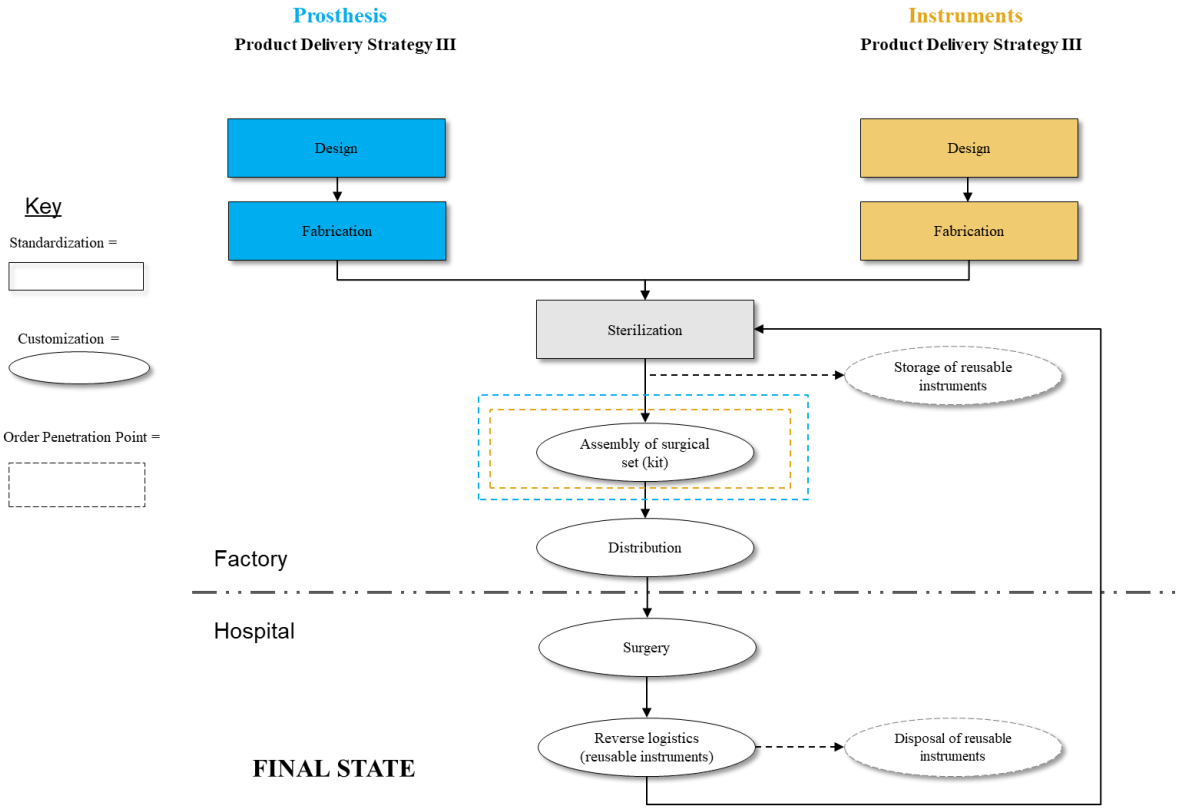


Figure 7 Modification of mass customization processes and decoupling points in newly introduced Group 1: high-runners for customized prostheses (ATO) and standard instruments

7 Discussion

In the medical technology sector, the notion of 'value' is different from consumer products as Healthcare Technology Assessment (HTA) establishes the value and cost effectiveness of technologies considering the clinical benefit to the patient relative to alternative products (Luce *et al.*, 2010). Commissioners of healthcare only procure medical technologies that meet regulated standards of quality and consistency and offer sufficient value. Medical technology companies therefore need to demonstrate value-for-money for alternative products in terms of

Health Technology Assessment as well as including healthcare professionals in the co-design of products that meet the clinical needs of patients. More expensive customized products need to provide additional value compared to standardized products and competitive products. The commissioners of healthcare make selection decisions that involve trade-offs between cost, clinical value, lead-time, recovery time and the level of interaction between medical device suppliers and healthcare professionals.

The research analysed how the product delivery strategies and processes could be understood using the Product Delivery Strategies conceptual framework developed in Section 3, to establish how product delivery and mass-customization theories could enhance the value proposition of medical technology products and improve performance and competitiveness (see Table 4). Initially the Company produced two families of products: 1) tailored customization (MTO, product delivery strategy IV); 2) patient-sized (ETO, product delivery strategy V); which were supplied as kits with the necessary instruments. Table 5 summaries the position of the initial and final state of the case company's product groupings in these frameworks (Lampel and Mintzberg, 1996; Gilmore and Pine, 1997; Yang *et al.*, 2007; Gunasekaran and Ngai, 2009; Qi *et al.*, 2020). The analysis identified that the first product family include a mix of high-volume standardised products (high runners) and a lower volume of standardised products that required more tailoring (low runners) that were separated into two groups.

The key features of the new *Group 1 – high runners,* included shifting the OPP to the 'assembly' (surgical kit) level (ATO, product delivery strategy III), which required moving away from a focus on pure *customization cost efficiency* to *customization responsiveness* to minimize order lead-time. The transformation also involved making a distinction from the company's strategy of *production postponement* (keeping customer-neutral work-in-progress that can be used to flexibly produce products that satisfy demand) to make room for *logistics postponement* (through *form postponement*), which delayed finalising the configuration of the finished product (surgical kit) within the manufacturing system until user demand is known (Yang *et al.*, 2004; MacCarthy and Brabazon, 2006). The management of products belonging to new *Group 2 – low runners* (tailored prosthesis), was not changed, meaning that they were still manufactured on a MTO approach, with a focus placed on producing order-neutral parts until customer differentiation was required at the manufacturing level – i.e., *production postponement* (Yang *et al.*, 2004; MacCarthy and Brabazon, 2006) to achieve *customization cost efficiency* (Qi *et al.*, 2020). In later stages of the value creation process, *transparent*

Literature	Product Delivery Strategies	CASE COMPANY'S INITIAL STATE					CASE COMPANY'S FINAL STATE						
		Product Group 1 - Tailored customized products		Product Group 2 - Patient-sized products			Product Group 1 - High runners		Product Group 2 - Low runners		Product Group 3 - Patient-sized products		
		Tailored prostheses	Standard instruments needed for operation (tailored prostheses)	Pure customized prosthesis	Standard instruments for operation (pure customized prosthesis)	Engineered instruments for operation (pure customized prosthesis)	Customized standard prosthesis	Standard instruments needed for operation (customized and tailored prosthesis)	Tailored prosthesis	Standard instruments needed for operation (customized and tailored prosthesis)	Pure customized prosthesis	Standard instruments for operation (pure customized prosthesis)	Engineered instruments for operation (pure customized prosthesis)
Marucheck and McClelland (1986)	MTS												
	ATO		X		X		X	X		X		X	
	MTO	X							X				
	ETO			X		X					X		X
Lampel and Mintzberg (1996)	Pure standardization												
	Segmented standardization												
	Customized standardization		X		X		X	X		X		X	
	Tailored customized	X							X				
	Pure customization			X		X					X		X
Gilmore and Pine (1997)	Adaptive customization												
	Transparent customization	X	X		X		X	X	X	X		X	
	Cosmetic customization												
	Collaborative customization			X		X					X		X
Yang et al., (2007)	Make to forecast				X			X				X	
	Logistics postponement		X				X			X			
	Production postponement	X							X				
	Purchasing postponement												
	Product development postponement			X		X					X		X
Gunasekaran and Ngai (2009)	BTF						X						
	BTO	X	X	X	X	X		X	X	X	X	X	X
	Configuration-to-order												
Qi et al (2020)	High volume customization												
	Customization cost efficiency	X							X				
	Customization responsiveness		X		X		X	X		X		X	
	Customization quality			X		X					X		X

Table 5: Summary of theoretical approaches and their application at the Case Company

customization was achieved with the addition of appropriate instruments during the assembly of the surgical kit (Gilmore and Pine, 1997).

Finally, a third product delivery strategy labelled patient-sized products (product group 3) was based on product delivery strategy V (ETO) (see Table 5). The more standardized products have lower costs and shorter delivery lead-times, but also have lower value in terms of clinical effectiveness, the useful life of the product and the patient experience. The patient-sized (ETO) products are an example of where high-quality and innovative products with a higher initial price can generate superior value over alternatives (Graves, 2011) leading to operational value (Darzi, 2008; Young and McClean, 2008) and value for money (Smith, 2009). For tailored prostheses the hospital stay for patients is usually 4 days following an operation and then full recovery takes 3-4 months. However, if the patient receives a pure customized prosthesis (ETO) rehabilitation is usually quicker, providing a heath gain (Smith, 2009). The quality of life experienced is also greater as 'more normal' movement is restored compared to tailored customized prosthesis (product delivery strategy IV (MTO)) or customized standardized prostheses (product delivery strategy III (ATO)) (Zeller *et al.*, 2017). The provision of patient-sized prosthesis requires close relationships and information sharing between the clinic and the medical device supplier. The additional value arises from both the augmentation of the product and relational value.

The product delivery strategies conceptual framework supported the Company to re-configure its processes; however, the framework did not consider the circular economy that is embedded within the medical technology industry. The key reverse logistics element the Company had to manage as part of its production strategies related to the return, sterilization, and the re-use of instruments. These returned instruments would form inputs into future products, so the research also helped to identify and manage what instruments need to be bundled with which products. For example, a patient would attend multiple clinics, and an order would be placed after the decision had been taken to select a tailored customized or patient-sized prothesis. These were evaluated to develop a revised configuration to reduce inventory, lead-times and costs, whilst simultaneously increasing capacity utilization and delivery performance. The case company applied the principles proposed in the conceptual framework outlined in section 3 (Figure 3) to also reconfigure processes for instrument manufacture and re-use. In the implementation workshops, particular attention was placed on what products could be produced using delivery strategy type III (ATO), IV (MTO), and V (ETO). The re-configured process for instruments is also shown in Figure 7. The management of logistics associated with instruments augmented all of the product families and provided additional relational value (Levitt, 1980; Ulaga and Eggert, 2006).

Cattani *et al.* (2010) proposed a hybrid manufacturing approach 'Spackling' where standardised production was re-shored from low-cost economies and was used to fill capacity when the demand for customized products was insufficient to fully utilise resources. Lawson *et al.* (2018) considered multi-model BTO/BTF approaches in the automotive industry. In this research, the redesigned product delivery strategies led to a hybrid manufacturing approach at the company level that combined product delivery strategies III, IV and V (ATO, MTO and

ETO) with a focused strategy (Skinner 1974) within the factory. This approach included the co-design of products with healthcare professionals and also the provision of a logistics service and recycling of instruments. The analysis of KPIs concluded that this was a successful strategy that increased value, whilst reducing lead-times and costs.

7.1 Reflection on action research implementation

Following recent practice in reporting on AR studies (Formentini *et al.*, 2019; Touboulic and McCarthy, 2020) a brief reflection is presented here. It is important to reflect on practice as it allows a researcher to consider the value of the research to stakeholders/participants (contribution to practice), researchers (contribution to theory and method) as well as developing an understanding of the broader context (Touboulic and McCarthy, 2020). The case company produces both standardized and 'patient-sized' prosthesis and provides additional value to hospitals and clinics by providing instruments and managing the logistics associated with their return. The challenge for management was to try to increase customer orders to increase profit but also to improve operational performance to reduce costs and lead times. The Company required clear production and product delivery strategies and KPIs to meet the requirements of different market segments.

The Action Research Strategy involved working with a wide range of internal and external stakeholders (see Appendix B). The Action Research project enabled a community of practice to be formed which promoted dialogue, shared reflection and learning. The stakeholders gained an understanding of different product delivery strategies and where value was being created. It also identified where parts of the process could be more standardized. The researchers and stakeholders reflected on the suitability of theoretical frameworks relating to value and product delivery strategies from practical and theoretical perspectives. This enabled the development of the new theoretical framework shown in Figure 3. From a practical perspective it enabled the systematic redesign of processes which reduced inventory, reduced delivery lead-times and increased capacity utilization. It also introduced the measurement and management of sales forecasting accuracy. It was found that change management was a major factor in implementation and stabilisation of the new product delivery strategies. Two of the main difficulties encountered during implementation were resistance to change from employees and lack of transparency in project communication, factors recognised by Kotter (1996). These issues also extended to suppliers. The concept of 'information loss' was important during this AR project because when project team members were not available for meetings, inadequately prepared secondary representatives attended. This problem was usually resolved later by additional project meetings, which while not ideal, were a workable solution. Senior managers considering such implementations would be advised to be cognisant of these critical, practical issues. The solution to these issues lay in the difficult task of enabling the managers, staff members, and their external partners to see the benefits of collaborating towards a common goal. This allowed management to see changes to processes in a more positive light, rather than as an additional burden.

One of the challenges of this Action Research process was to generalize the product delivery

strategy framework as opposed to just considering the production of prothesis. Whilst the study finished at month 12 in terms of monitoring of the KPIs, there were subsequent targets to improve on these year-on-year, which may lead to further performance improvements.

8 Conclusions

The literature on product delivery strategies and mass customization has largely related to products that are chosen by customers based perceived value. In healthcare the commissioner of healthcare is normally an insurance company or a health service that evaluates value objectively in terms of clinical outcomes and cost savings using Health Technology Assessment. The various product delivery strategies represent different trade-offs in terms of costs, lead times, clinical outcomes and patient experience. The provision of medical devices and the associated services requires considerable co-design and collaboration between manufacturers and healthcare professionals. The literature has not considered product delivery and mass customization in this context. This work has therefore considered how product delivery strategies and mass-customization theories can be used to enhance the value propositions for medical technology products as well as improving performance and competitiveness. A holistic conceptual framework (Fig. 3) was developed, integrating previous theories with outcomes in terms of value and lead-times. The framework was used to inform the redesign of processes at a medical technology company. The identification of product groupings with similar requirements and characteristics enabled a focused strategy to be employed that, from a practical perspective, reduced costs and lead-times, whilst increasing capacity utilisation and delivery performance. The value proposition was augmented by providing kits that included the instruments required for operations together with a logistics service that managed the supply and recycling of instruments. This servitization strategy provided additional relational value for both the company and healthcare providers.

The value of this work to practice is that it demonstrates that the complexities associated with product customization can be understood in terms in terms of a holistic model of product delivery strategies that provides a framework for the redesign of processes. The work is relevant to industries where there are trade-offs between standardized products and customized products that require co-design including considerable efforts in the management of implementation. Further work could include practical application of the conceptual framework demonstrating additional cases, and in other settings and industries. Further theoretical exploration of the issues concerning information loss during implementation would also be valuable.

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Appendix A

Roles of the researchers	**Features**
Moderation	• Ensure that the voices of all participants are heard, including contradictory ideas and points of view. • Ensure that the outcomes of all workshops deliver a tangible result to the project's success. • Ensure that discussions remain focused. • Capture and record important points and ensure that they are not missed during the discussions.
Speed	• Ensure that the project schedule is on track. • Ensure that all workshops are appropriately prepared and followed up. • Ensure that all tasks and activities are finished in due date.
Know-how transfer	• Bring in new ideas and points of view. • Deliver new approaches, own experiences in the field. • Design and implement changes according to a structured roadmap.
Drivers for change	• Address strategic points to management to remove barriers for change. • Anticipate risks and manage change. • Establish an appropriate project governance. • Define and install necessary elements to ensure sustainability.

Appendix B

A Detailed Account of the Action Research Project

Phase	Content

Diagnosing	• The diagnosing phase consisted of three main elements: two workshops and an interview series.
	• Management workshop:
	  o The workshop was conducted with top management to identify key issues, formulate practical and theoretical objectives for the action research project, and prioritize areas of opportunity.
	  o Researchers were involved both as participants and moderators of the meetings.
	  o The management workshop helped to develop an understanding of the drivers that had an influence on the identified issues, opened a dialogue space to gather different standpoints, and gain buy-in.
	  o During the diagnosis, management reflected about its extant production strategy and inventory management practices.
	  o A detailed action plan was defined with the management team.
	• Interview series:
	  o The purpose of the interviews was to gather the viewpoints of all involved parties. This also included an analysis of the extant business practices and processes.
	  o Both quantitative aspects such as the case organization's KPIs as well as qualitative aspects such as the degree of cooperation of the departments in the planning process were evaluated.
	  o Key finding: manufacturing was triggered almost exclusively by plans generated by the ERP-System, except for backlogs and return deliveries, which were either communicated via E-mail, phone, or directly to the master scheduling department by the sales department.
	• Mapping workshop:
	  o Analysis of product portfolio
	  o Detailed as-is process mapping

Action Planning	• Future processes were designed based on the insights gained during the interviews with the main process stakeholders and recommendations from relevant literature. • To define the future process, eight participative workshops took place, with the researchers collaborating with members of the organization. The case company's master scheduling manager was appointed as the project manager for the implementation. • Based on an analysis of the product portfolio (prothesis and instruments), customer order patterns were identified, and product groups were formed (high runners, low runners, design/prototype products).

Phase	Content
	• The Order Penetration Point for each one of these products was defined following theoretical recommendations, which helped to develop a manufacturing strategy for each group. • The portfolio of surgical instruments was analyzed to streamline the number of variants. • A summary of objectives, responsibilities and procedures for the complete process was developed with the team.
Action Taking	• The core challenges during the action taking phase were: (1) to ensure a sustainable change and (2) to convince the staff of the necessity of the new processes. • This phase was conducted with participative workshops, comprising of comprehensive training programs, test runs, coaching, and implementation monitoring. • Key milestones during the action taking phase: o **Operational Kick-off meeting.** Participants were senior management and the departments involved in the process. In this meeting, project objectives, deliverables, and methodology were restated and agreed upon. o **Theoretical training sessions.** To introduce the project team to the core principles of OPP, a daily training session was held for the project team and for other key operating managers. In these sessions, the future process was explained, inputs and expected outcomes of each process step were presented, and roles and responsibilities for each process step were declared. o **Review of implementation results.** This management review meeting was set up to review progress and for the management of the case organization to make appropriate decisions to ensure the success of the project. In this presentation, the status of the project KPIs was presented, barriers for implementation were addressed and discussed, and important decisions were taken. o **Review of stabilization results.** The KPIs presented in this management review presentation delivered a much positive picture on the implementations made by the project team, as the team internalized and felt more comfortable with their roles and responsibilities, were given sufficient time to prepare presentation materials, and several critical action items were successfully implemented.
Evaluating	• KPIs were measured on a weekly basis and reflected upon every month. These were 'Total Inventory', 'Inventory Turnover', 'Days of Inventory Outstanding', 'On-Time-In-Full', 'Backorders', 'Capacity Utilization', 'Average Lead Time', 'Sales Forecast Accuracy'. • None of the targets defined by management were met in the first nine months after the start of the Action Taking phase, thus requiring a slight adjustment of the concepts at an operations level. • On month 12 of the intervention, targets were met and/or exceeded, thus providing factual evidence of the successful implementation of the changes.

Phase	Content
	• Actions were derived based on the KPI development.
Specifying Learning	• Key project participants were invited to reflect upon the learnings of the action research study in two sessions (one participative workshop and one management presentation). • The theories of mass customization, postponement and group technology were applied to reduce inventory and lead times while increasing capacity utilization and delivery performance. • Extant theoretical models were not able to fully explain the complexity of the findings in the case organization. For this reason, a new framework was developed and applied, combining the work of Marucheck and McClelland (1986), Lampel and Mintzberg (1996), Gilmore and Pine (1997), Yang et al. (2007), Gunasekaran and Ngai (2009) and Qi *et al.* (2020). • The framework was successful in the case organization, as it supported decisions on product segmentation according to the products' value proposition. • The framework also allowed improved processes to be developed for customized standardized, tailored customized and pure customization products.

Appendix C

Excerpts from Coding and Coding Tree developed in Stage 1: Diagnosing

Raw data themes	Codes	Categories
"The fact is, clinicians are not really interested in knowing how much it cost us to develop and manufacture our devices, even if they contribute to their development. Clinicians judge our products and solutions based on how much value we can deliver for them. Value not only in terms of the technical solution developed, but in terms of shorter time-to-market as well. Our success is measured on how well we can really understand our clients' needs and develop solutions that match these needs (I10, 2015)."	Perceived value by the customer	Product development
"However, we know that our core know-how must be protected at all costs. This is why you see in our manufacturing shop that we really produce the complete devices by ourselves. No components are manufactured elsewhere, even if it would make sense for other companies to outsource these operations offshore (I4, 2015)."	Technological capability	Product development
"Long-term engagement with suppliers is a must in our business, especially for minerals such as titanium. As we work with a high-quality standard, we require from our suppliers to deliver us only materials that meet these standards. We handpick our suppliers and only work with those that have been certified by us (I17, 2015)."	Supplier selection and certification	Sourcing strategies

Table 6 Excerpts from coding

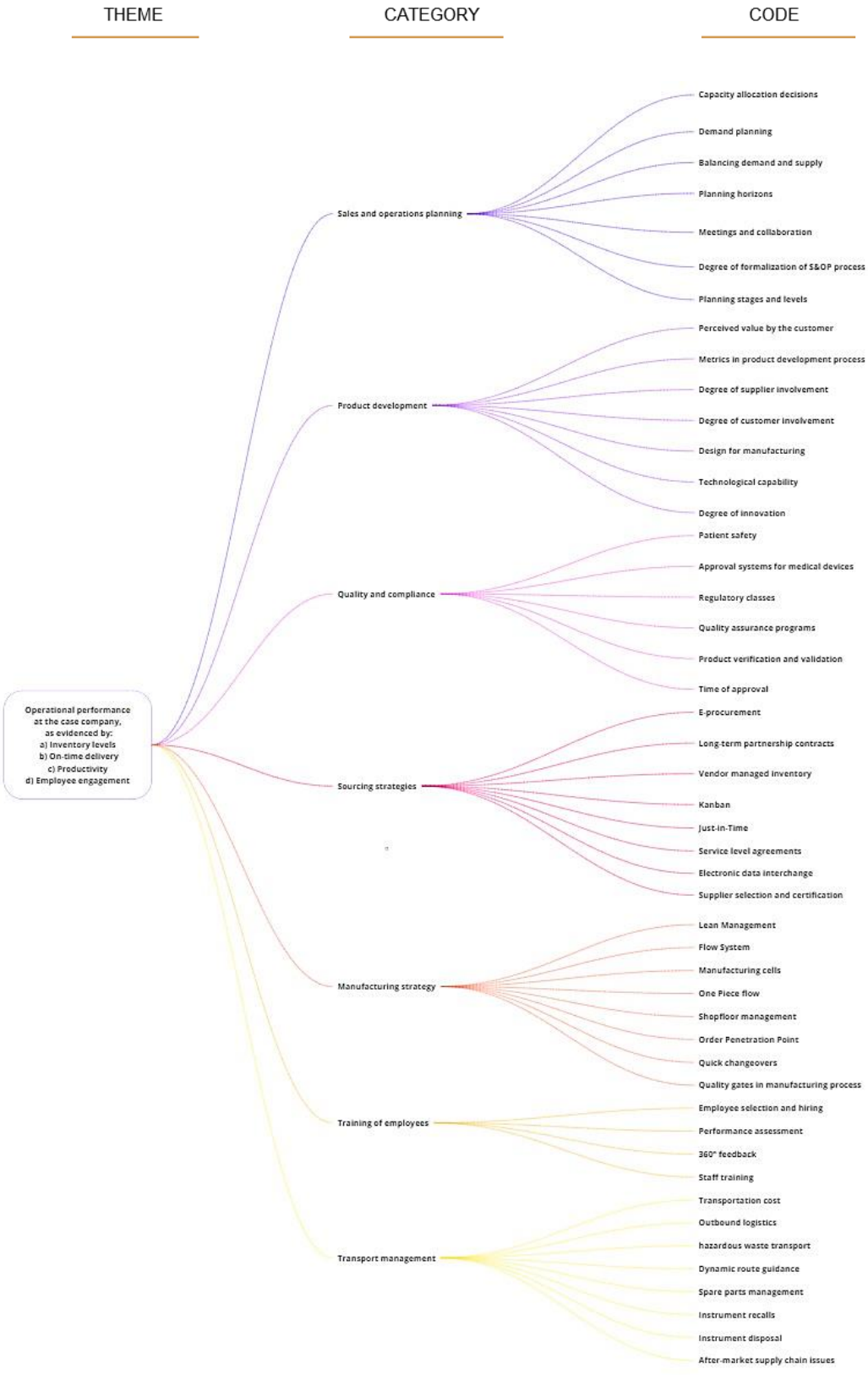

Table 7: Coding tree developed after the interview cycles in Stage 1: Diagnosing