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The moderating role of Lean Six Sigma practices on quality management practices and quality performance in medical device manufacturing industry

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Abstract

Purpose – The purpose of this paper is to explore the moderating role of Lean Six Sigma (LSS) practices in explaining the relationship between quality management practices (QMPs) and quality performance.

Design/methodology/approach – Partial least square-based structural equation modeling (PLS-SEM) was used to empirically examine the moderating effect of LSS practices on QMPs and quality performance in Malaysian medical device manufacturing companies.

Findings – Findings revealed that both QMPs and LSS practices have a significant and positive effect on quality performance. Furthermore, LSS practices served as a substitute for moderating the positive relationship between QMPs and quality performance in such a way that the relationship becomes weaker as LSS practices increase.

Originality/value – LSS is acknowledged as the most well-known hybrid methodology; however, due to its relative newness, it has not been studied in great detail. Unlike previous studies, this paper argued that Lean and Six Sigma practices are distinct from its predecessor TQM practices; moreover, both Lean and Six Sigma practices do not need to substitute QM/TQM practices instead of complimenting the QMPs. In addition, this study adds to the growing body of QM literature by empirically examine the effect of LSS practices in moderating the relationship between QMPs and quality performance.

Keywords Quality management, Lean Six Sigma, Manufacturing

Paper type Research paper

1. Introduction

Unlike pharmaceutical drugs (i.e. Chiarini, 2012), medical device is identified as an instrument, apparatus, implement, machine, implant, *in vitro* reagent or other similar or related article whether it is used alone or in combination with software, hardware or any accessories (FDA, 2019). Each of the components within the system can influence the performance of the device, thus, the quality and reliability of the medical device cannot be compromised since it is closely tied to patient's safety and well-being (FDA, 2011). The survival of the fittest in a highly competitive marketplace is contingent on safeguarding the



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product conformity and consistently yielding medical devices of required safety standards. With the ever-increasing complexity of design to process development, staying competitive and meeting the medical needs of aging population appears to be challenging (Jamshidi *et al.*, 2014). Offering a better, cheaper and safer life-enhancing and life-saving medical device is the ultimate quest of every medical device manufacturing (MDM) company. Malaysia has emerged as the largest medical device market in Southeast Asia, with a market worth US$1.55bn (MIDA, 2020). The growth in the MDM industry is expected to have a positive impact on the Malaysian economy with no sign of slowing despite gloomier global economic forecasts (CodeBlue, 2020). To remain competitive and relevant in the global market, MDM companies are encouraged to undertake and implement best quality practices to improve quality performance subsequently leading to cost savings with lesser defects rate, lesser waste and fewer customer complaints.

In recent years, there is a growing trend toward the integration of Lean Six Sigma (LSS) practices across all industries as a viable process improvement methodology to achieve the competitive priorities of quality, cost, speed and flexibility (Chiarini, 2012; Chiarini and Baccarani, 2016; Singh and Rathi, 2019; Rodgers and Antony, 2019; Muganyi *et al.*, 2019; Rodgers *et al.*, 2021). The roots for Lean and Six Sigma practices can be traced back to when manufacturers were facing great pressure to achieve ideal quality and speed (Corbett, 2011; Shokri, 2017). TQM, Lean and Six Sigma practices have gained recognition as effective continuous improvement methodology with similar ultimate aims that is to attain desired optimum quality performance, waste reduction and eliminate process variation subsequently enhance customer satisfaction (Andersson *et al.*, 2006; Muganyi *et al.*, 2019). Yet, numerous studies revealed that despite the successful execution of quality management practices (QMPs), companies failed to achieve the anticipated result hence a debate into its effectiveness was set in motion (Eriksson, 2016). Moreover, the findings of prior QM-performance literature are contradicting in nature (Arumugam *et al.*, 2008; Asif *et al.*, 2009; Talib *et al.*, 2013; Psomas and Kafetzopoulos, 2014; Patyal and Koilakuntla, 2017) which had raised an important question as whether QMPs alone are sufficient to achieve promising quality performance.

Despite the growing interest of TQM companies in LSS practices (Habidin *et al.*, 2016), previous literature has failed to examine the complementarity effect of LSS practices and QMPs on quality performance. Furthermore, a recent review of industrial literature has revealed numerous gaps and shortcomings. First, although considerable progress has been made in the field of QM/TQM in general, Lean and Six Sigma practices in particular, many issues remain unexplored, especially concerning the similarities and differences between these concepts. A case in point, Zu *et al.* (2008) had pointed out that Six Sigma practices are evidently distinguishable from its predecessor TQM with three distinct dimensions complementing TQM practices to improve organizational performance. Likewise, Parast (2011) highlighted the significant differences between Six Sigma and TQM in its unique capability toward problem-solving and exploration. Despite that, earlier studies revealed that the measurement for Six Sigma practices overlapped with TQM practices (Shafer and Moeller, 2012). In addition, Lean differs from its closest relative TQM at the operational level given that Lean is not cyclical in nature and TQM does not emphasize in optimizing the process flow as well as the elimination of non-value added activities (Andersson *et al.*, 2006; Pettersen, 2009; Mousa, 2013; Drohomeretski *et al.*, 2014). Building on the above arguments, this study proposed that Lean and Six Sigma practices are a management concept of its own and are evidently distinct from its predecessor TQM practices.

In addition, the review of the literature suggested that Six Sigma practices do not need to substitute TQM instead of strengthening and complimenting it (Revere and Black, 2003). Similarly, Drohomeretski *et al.* (2014) implied that Six Sigma is not an alternative to TQM; in fact, the integration of Six Sigma and TQM practices enables an organization to gain a

competitive advantage. Furthermore, earlier studies on the joint effect of Six Sigma and TQM practices had revealed that Six Sigma practices positively influence organization's quality performance via supporting the traditional quality practices (Zu *et al.*, 2008; Sin *et al.*, 2010). Integrating Six Sigma practices with TQM can improve quality without significantly increasing the cost of operations (Patyal and Koilakuntla, 2015). Echoing the above arguments, numerous scholars had rooted for the integration of Six Sigma and TQM, as its combined effect is greater than the sum of individual effects (Ricondo and Viles, 2005; Patyal and Koilakuntla, 2015). Over and above, Furlan *et al.* (2011) who examined the complementarity effect of Lean and TQM practices had suggested that both practices should be used in a complementary fashion to achieve superior performance. Lean should act as a supportive role for TQM practices rather than an alternative (Dahlgaard and Mi Dahlgaard-Park, 2006; Drohomeretski *et al.*, 2014). Moreover, Chiarini (2011) who carried out a nine-year study in European companies revealed that integrating Lean thinking into ISO 9001 allowed an organization to increase its process efficiency.

Both methodology-focused Six Sigma (Revere and Black, 2003; Zu *et al.*, 2008; Zu, 2009; Ngo, 2010) and Lean practices (Dahlgaard and Mi Dahlgaard-Park, 2006; Mousa, 2013; Drohomeretski *et al.*, 2014) cannot be ignored in the process of QM implementation given that effective execution of Lean and Six Sigma practices complements QM practices in improving quality performance. TQM and Lean and Six Sigma practices should be used in a complementary fashion and executing these concepts altogether can produce a great deal of advantages for an organization (Andersson *et al.*, 2006). Lean and Six Sigma practices do not need to substitute TQM practices instead of complimenting and strengthening the QM program (Revere and Black, 2003; Mousa, 2013; Drohomeretski *et al.*, 2014; Patyal and Koilakuntla, 2015). Into the bargain, Chan *et al.* (2014) implied that there is a growing need to implement LSS practices in the QM environment to improve process/product quality performance by reducing process variation while simultaneously eliminating waste. Hence, in accordance with previous works, this paper argued that LSS practices do not need to substitute TQM practices instead of strengthening the QMPs in its initiatives to improve quality performance.

Furthermore, a recent study by Sim *et al.* (2022) has revealed that the majority of previous LSS studies are either conceptual articles or mainly seek to identify the critical success factor of LSS practices. Despite the growing prevalence of LSS practices, the related works in validating the positive influence of LSS practices on quality performance remain in its infancy stage (Corbett, 2011; Albliwi *et al.*, 2015; Habidin *et al.*, 2016; Rodgers *et al.*, 2021; Sim *et al.*, 2022). Hence, the objective for this paper is to empirically examine the moderating effect of LSS practices between QMPs and quality performance which has been insufficiently explored. In particular, this paper intends to examine the role of LSS practices as a moderator which are expected to alter the magnitude of a causal relationship between QMPs and quality performance. The remainder of this paper is organized as follows. Section 2 presents the literature review on QMPs, LSS practices and followed by the hypothesis development for the proposed model where the supporting arguments for relationship between QMPs, LSS practices and quality performance are presented. Section 3 describes the research methodology and followed by the presentation of results and data analysis in Section 4. In Section 5, the findings and discussions are discussed. Lastly, Section 6 provides further discussion on conclusions, research implications, limitations and future research directions.

2. Literature review

2.1 Quality management practices

Grounding on sociotechnical system (STS) theory, this paper argued that the effectiveness of QM implementation is dependent on the jointly optimization of infrastructure QMPs (social

subsystems) and core QMPs (technical subsystems) rather than independent of each other (Kaynak, 2003; Zu, 2009; Grijalvo, 2012). Intrinsically, STS theory views QMPs as an integrated STS, allowing the classifications of QMPs into infrastructure QMPs and core QMPs and lastly supports the theoretical argument that pointing toward the expected synergy between the two sets of practices instead of solely dependent on either infrastructure QMPs or core QMPs. In the same vein, the successful implementation of QMPs is determined by the integration of all QM practices and not a subset of them as there is a strong interdependency between QM practices (Flynn *et al.*, 1994; Kaynak, 2003; Nair, 2006; Zu, 2009; Kim *et al.*, 2012). For this paper, six most frequently cited dimensions of QMPs in previous QM/TQM literature were selected, namely, leadership, process management, employee management and training, customer relationship management, supplier quality management and product design and control. The adoption of these six dimensions of QMPs were attributed to numerous aspects. First, these dimensions were widely accepted and frequently cited in previous QM/TQM literature as the critical factors of QMPs (Zu, 2009; Miller *et al.*, 2009; Kim *et al.*, 2012). Additionally, given that the industry of focus for this study lies specifically in the MDM industry with both ISO13485 and FDA quality standard emphasizing the significance of incorporating design control to ensure the quality performance of medical devices thus product design and control will be considered in this study despite it is infrequently embraced by QM scholars. Moreover, all these dimensions are consistent with the enablers of Malcolm Baldrige National Quality Award (MBNQA) criteria and EFQM Excellence Model hence would constitute a valid representation of QMPs (Escrig-Tena *et al.*, 2011; Gómez *et al.*, 2017). Last of all, both ISO13485 and FDA 21 CFR Part 820 quality standards had emphasized on the importance of incorporating all these six dimensions of QMPs to sustain and improve the quality performance in the MDM industry.

Leadership who actively partake in continuous process improvement initiatives and with the ability to lead a firm in pursuing a common quality goal is a prerequisite for effective QMPs implementation (Mellat-Parast *et al.*, 2011; Bani-Hani and Al-Omari, 2012; Patyal and Koilakuntla, 2015; Wu, 2015). Next, process management monitors, controls and performs periodic preventive maintenance to minimize production interruptions and reduce process variations with the use of statistical process control tools and techniques (Kristal *et al.*, 2010; Zeng *et al.*, 2013; Patyal and Koilakuntla, 2017). Employee management and training programs are of tremendous importance in the pursuit of successful QMPs to ensure all employees are alert to all the requirements and know-how in incorporating quality system procedures into optimizing production processes (Łuczak and Wolniak, 2015; Mehra and Coleman, 2016). Subsequently, customer relationship management channels the voice of customer, attending to customer feedback and incorporating it into product design, as well as monitoring customer satisfaction and responding to customer complaints (Jayaram *et al.*, 2012; Shan *et al.*, 2013). In addition, supplier quality management involves developing a long-term relationship with the suppliers and evaluating suppliers' quality capabilities seeing as the complexity of purchased parts increased dramatically hence interdependencies with suppliers and their reliability became crucial (Weckenmann *et al.*, 2015). Lastly, product design and control give emphasis to designing the quality properties of medical products in meeting the different wants and needs of customers (Shan *et al.*, 2013).

2.2 Lean manufacturing practices

Lean manufacturing practices direct a firm to enhance its process efficiency via the elimination of waste and non-value-added steps simultaneously improves the speed and flow of the value stream (Campos, 2013; Saini and Sujata, 2013; Burch *et al.*, 2016; Lawless, 2016; Singh and Rathi, 2019; Asif, 2021). In line with prior studies, this paper proposed that Lean manufacturing practices are a methodology encompassed of four distinct dimensions, namely, just-in-time (JIT), pull production system, flow management and setup time

reduction (Shah and Ward, 2003, 2007; Jayaram *et al.*, 2008; Rahman *et al.*, 2010; Agus and Hajinoor, 2012; Sim *et al.*, 2022). JIT originates from the concept of reducing inventory holding and ensures each process is provided with the right parts and components in the exact quantity and at the right time (Jayaram *et al.*, 2008; Rahman *et al.*, 2010; Agus and Hajinoor, 2012; Pacheco *et al.*, 2015). Pull-production systems are highly supported by JIT (Levy, 1997), emphasizing small and frequent deliveries of raw materials from suppliers or work-in-progress to be delivered JIT whenever the downstream workstation needs it (Lee and Ebrahimpour, 1984; Agus and Hajinoor, 2012). Pull-production system regulates the flow of resources driven by the demand from downstream (customer) unlike traditional batch-based production where production is pushed from upstream to downstream by a production schedule (Agus and Hajinoor, 2012; Chavez *et al.*, 2013). Pull production system is governed based on actual consumption, low inventories, better communications between workstation and management by sight to prevent the overflow of work-in-process inventory (Shah and Ward, 2003, 2007; Agus and Hajinoor, 2012; Khanchanapong *et al.*, 2014). Next, flow management reduced operations time and works-in-progress with the concept of one-piece flow and small lot sizes production (Agus and Hajinoor, 2012). An efficient cellular layout ensures smooth material flow and material handling accompanied by quick changeover of equipment will enhance a firm's flexibility to react to demand changes and/or product mix (Nawanir *et al.*, 2013; Khanchanapong *et al.*, 2014). Setup time reduction aims at optimizing the conversion period for a given process in the most efficient manner which will require the changing of physical layout for a process and having all materials and tools readily available (Agus and Hajinoor, 2012). In brief, Lean manufacturing practices comprise highly inter-related practices that work together synergistically to reduce the lead time of work-in-process inventories and manufacture finished products at the pace of customer demand with little or no wastes (Shah and Ward, 2003, 2007).

2.3 Six Sigma practices

Six Sigma is a data-driven decision-making tool with the ultimate aim of reducing defect rate and process variation (Campos, 2013; Pacheco *et al.*, 2015; Sunder, 2016; Asif, 2021). In line with previous studies, this paper proposed that Six Sigma practices are composed of three distinct dimensions, namely, Six Sigma Role Structure, Six Sigma Structured Improvement Procedure and Six Sigma Focus On Metrics (Zu *et al.*, 2008; Parast, 2011; Shafer and Moeller, 2012; Patyal and Koilakuntla, 2015; Sim *et al.*, 2022). Six Sigma has a well-defined hierarchy of process improvement specialists known as Six Sigma role structure and is typically referred to as champions, master black belts, black belts and green belts (Linderman *et al.*, 2003; Zu *et al.*, 2008). Six Sigma role structure is a distinctive characteristic of Six Sigma practices where specialists are assigned to take different levels of roles and responsibilities in leading the continuous quality improvement efforts (Linderman *et al.*, 2003; Snee and Hoerl, 2003; Sinha and Van de Ven, 2005; Zu *et al.*, 2008). For Six Sigma Structured Improvement Procedure, DMAIC/DMADV models provide a standardized methodological framework to guide the quality teams during the conduct of carrying out project improvement and design planning (Zu *et al.*, 2008). Define–Measure–Analyze–Improve–Control (DMAIC) model aims at supporting existing process improvement, whereas Define–Measure–Analyze–Design–Verify (DMADV) model focuses on the development of new product/service design improvement with a combination of a well-defined set of tools which are applied at various phases (Zu *et al.*, 2008). Six Sigma practices strive to identify base problems (define); carry out data collection (measure); determine the roots of problems (check); adopt improvement actions (action); and maintaining (control) the process (Pacheco *et al.*, 2015). Next, Six Sigma focus on metrics relies on the availability of accurate and timely quality information to reliably gauge processes, thereby allowing quality teams to closely monitor the process improvement activities throughout its entire product life cycle (Zu *et al.*, 2008; Sin *et al.*, 2010).

Focusing on quantifiable metrics such as defects per million opportunities (DPMO), critical to quality (CTQ), defect measures, process sigma level and so forth give rise to breakthrough in process and quality improvement (Linderman *et al.*, 2003; Zu *et al.*, 2008; Patyal and Koilakuntla, 2015).

2.4 Lean Six Sigma practices

Lean Six Sigma practices have been acknowledged as a more robust methodology that integrates both Lean and Six Sigma by exploiting the value-maximizing philosophy of Lean in removing non-value added process and enhanced by data-driven Six Sigma methodology (Niu and Fan, 2015; Singh and Rathi, 2019; Sunder *et al.*, 2018; Asif, 2021). Six Sigma practices do not address process flow optimization and waste elimination, in addition, Lean does not possess the quality tools to perform statistical control in reducing process variation and defects rate hence Lean and Six Sigma practices complement each other by overcoming individual shortfalls (Sim *et al.*, 2022). The integration of Lean and Six Sigma allow a company to have the best of both world with Lean focuses on improving the flow in value stream and reduction of lead time while Six Sigma focuses primarily on reducing process variation (Albliwi *et al.*, 2015; Pacheco *et al.*, 2015; Sunder, 2016; Swarnakar and Vinodh, 2016; Scheller *et al.*, 2018; Moya *et al.*, 2019; Muganyi *et al.*, 2019; Walter and Paladini, 2019; Alblooshi *et al.*, 2021). Lean Six Sigma practices integrate Lean's speed and waste reduction characteristics simultaneously exploiting Six Sigma statistical data-driven decision-making tool for process improvement (Alnadi and McLaughlin, 2021; Asif, 2021). LSS practices direct a firm toward better quality performance via removal of process variability, cause of defects, non-value added activities and waste elimination, which subsequently decrease cycle time efficiently (Drohomeretski *et al.*, 2014; Knapp, 2015; Albliwi *et al.*, 2017; Alblooshi *et al.*, 2021). The integration of Lean and Six Sigma practices into a single approach allows the company to get things done faster, better, cheaper, safer and greener (Pacheco *et al.*, 2015; Singh and Rathi, 2019). Furthermore, the blending of Lean and Six Sigma methodologies enable a company to address both the quality and speed simultaneously via the elimination of defect rate, process variation, waste elimination and cycle time reduction (Sim *et al.*, 2022).

3. Hypothesis development

3.1 Moderating role of Lean Six Sigma practices between quality management practices and quality performance

Lean Six Sigma is an effective leadership development tool that directs top management in meeting organization goals to achieve high-quality outcomes, reduce defect rates and ensure the quality levels are maintained (Snee, 2010). Leadership commitment to quality coupled with endless support from top management in creating a supportive and positive work climate for LSS practices help to ensure the successful implementation of LSS practices and subsequently enhance the quality performance (Lawless, 2016; Sunder and Antony, 2018; Alnadi and McLaughlin, 2021). Next, the quality of constituent parts can have a decisive impact on finished products thus incorporating LSS practices into supplier quality management, which will enable suppliers to benefit from LSS tools in achieving operational excellence. Improving the quality of purchased materials eliminates variability and subsequently improved the quality performance. Furthermore, the use of Lean tools such as Kaizen, JIT and value stream mapping coupled with data-driven Six Sigma statistical tool in the process management allows the production to flow without interruption, minimizes non-value-added activities, reduces process variability and eliminates defect subsequently leading to process improvement and optimal quality performance (Snee, 2010; Corbett, 2011; Singh and Rathi, 2019). Moreover, investing LSS practices in employee training program has

shown to increase the quality performance in manufacturing settings (Lawless, 2016). The introduction of LSS practices into employee training program through the provision of black belt and green belt training as well as the engagement of employees in deploying LSS approach into everyday work has reflected in internal quality improvements (Corbett, 2011). LSS practices pave path for employee empowerment, creating an environment that positively encourage the empowered staffs at higher-level of process analysis to constantly improve process flow, eliminating waste and reducing process variation which ultimately leads to improved process and quality performance (Pepper and Spedding, 2010; Habidin and Yusof, 2013; Singh and Rathi, 2019; Asif, 2021).

To boot, companies can benefit from Six Sigma's focus data decision-making tools to understand the factors that drive customer satisfaction (Saraf and Yadav, 2012). Incorporating the use of LSS tools into customer relationship management helps to develop and refine the market segments via customers' feedback, comparative data and contextual information. Therefore, allowing the firms to be able to effectively respond to fast-changing customer requirements and adapt its processes accordingly to achieve high-quality products (Corbett, 2011; Jayaram *et al.*, 2012). Integrating LSS practices into customer relationship management optimized customer interactions and enhanced firm awareness of customer needs subsequently allows the integration of those needs into core processes thus improving quality performance. Over and above, integrating LSS tools into product design and control in addressing customer requirements by means of applying five phases of Design for Six Sigma methodology (DMADV) conjoined with Lean concepts into new product design improvement improves the product cycle time, cost-reduction, waste elimination and subsequently enhances product quality performance (Corbett, 2011). Incorporating LSS tools in translating the customer needs into products and services helps to better meet the customer's requirements (Sony *et al.*, 2020). To conclude, this study argued that LSS is a process improvement methodology that is applicable to all industries and at all stages of the product life cycle from servicing customers to the provision of employee training and empowerment, in addition to incorporating it into the process management, supplier quality management and product design and control. In line with the above arguments, this leads us to the following hypothesis:

H1. The positive relationship between QMPs and quality performance will be stronger when LSS practices are stronger.

4. Research methodology

4.1 Sample

For this paper, a thorough review of QM/TQM, Lean, Six Sigma and LSS literature followed by a pre-test administered to two academicians and one industrial LSS expert was conducted to ensure the content validity of the survey instrument (Bazera, 1996). In the present study, quality performance was measured in terms of product quality, percentage of scrap and rework rate, delivery performance, process variability, cycle time and customer satisfaction and the measurement items for both quality performance and QMPs are adapted from the survey instruments developed by Zu (2009) and Patyal and Koilakuntla (2015, 2017). Next, the measurement items for LSS practices are adapted from survey instruments developed by previous scholars such as Shah and Ward (2007), Zu *et al.* (2008), Ngo (2010), Rahman *et al.* (2010) and Nawanir *et al.* (2013). A "seven-point" Likert-type scale ranging from 1 to 7 was used to measure each item. During the pretest, all participants were asked to provide feedback concerning the relevant of the items in representing the constructs, and all comments received were revised accordingly. For pilot test evaluation, 40 respondents were chosen from the same pool of participants from which the sample for the full study will be

drawn to attain valuable insights and amendments are made before the survey instruments were released as the final version (Bradburn *et al.*, 2004). The research population for this study was targeted at MDM companies in Malaysia pooled from the list of the Association of Malaysian Medical Industries (AMMI) and Malaysian Investment Development Authority (MIDA). For this paper, non-probabilistic sampling strategy via the purposive sampling method is adopted. The purposive sampling technique when it is used properly can be just as effective, otherwise, more efficient than random sampling (Tongco, 2007). This is because the purposive sampling technique allows the researcher to identify the eligible respondents who possess a deep understanding of the research problem and, moreover, willing to provide the information by virtue of knowledge or experience (Bernard, 2002; Lewis and Sheppard, 2006; Tongco, 2007; Creswell *et al.*, 2011). On top, Rowley (2014) claimed that a probabilistic sample can be the representative of a population from which it is drawn as statistical generalizations about the population can be made. Every case within the population has a known probability of being included in the sample hence heightening the likelihood of selecting cases which represent the total population. The target or preferred respondents were those who were involved in continuous process improvement initiatives such as QM/TQM, Lean, Six Sigma and LSS practices. The participants of this survey were management representatives or those who possess equivalent roles as quality/operations managers, QA/QC engineers or process engineers within the manufacturing floor. For data collection, a multi-item scale Web-based self-administered questionnaire designed using Google Form was used as the primary tool. All the MDM companies were first approached through phone calls with an explanation of the purpose of this study as well as to get hold of the eligible respondents' email address and their consent to participate in this study. Subsequently, emails attached with cover letters and survey links were then sent to the respondents. A total of 164 copies of self-administered questionnaires were distributed to MDM companies in Malaysia with 103 returned and useable questionnaires. The sample size was deemed adequate as it is able to detect medium effect size at a statistical power of 80% using G*Power statistical tool (Hair *et al.*, 2014). Given that the emphasis of this paper is to estimate the path coefficient that maximizes the R^2 values of endogenous construct as well as an explanation of variance (Hair *et al.*, 2014; Ramayah *et al.*, 2018), in addition to, PLS-SEM allows the investigation of latent variable models at a higher level of abstraction hence PLS-SEM is deemed appropriate for data analysis (Becker *et al.*, 2012).

4.2 Measures

Hierarchical latent variable models or higher-order constructs are multidimensional constructs that exist at a higher level of abstraction and completely mediate the influence from or to their underlying dimensions (Chin, 1998; as cited in Becker *et al.*, 2012). Hierarchical latent variable models allow the matching of predictor and criterion variables at a similar level of abstraction (Becker *et al.*, 2012). Literally, hierarchical latent variables are characterized by the level of abstraction and the relationships between the constructs (formative vs reflective) in the model (Wetzels *et al.*, 2009). Higher-order construct does not exist without its lower-order constructs and it is either represented (reflective) or constituted (formative) by lower-order constructs (Becker *et al.*, 2012). In recent years, the modeling and estimation of hierarchical latent variable models using PLS-SEM has become increasingly prevalent (Sarstedt *et al.*, 2019). Previous scholars have proposed several methods to model the hierarchical latent variables using PLS-SEM, namely, the repeated indicators approach, sequential latent variable score method also known as the two-stage approach and hybrid approach (Becker *et al.*, 2012). Literature suggested that the repeated indicators approach may evoke artificially correlated residuals, producing biased and less consistent estimates in the case of a small sample size (Becker *et al.*, 2012). The two-stage approach reduces model complexity and allows for a more parsimonious model into the bargain with fewer paths that

need to be estimated and without the need for lower-order constructs (Becker *et al.*, 2012). Hence, for this study, the building of a higher-order construct using PLS-SEM is performed via a two-stage approach as proposed by Ringle *et al.* (2012). This method begins with estimating the latent variable scores (LVS) for first-order constructs in the absence of second-order construct subsequently the LVS obtained in the first-stage would serve as indicators for higher-order construct in a separate stage of model analysis (Wetzels *et al.*, 2009). For this study, the estimation and testing of hierarchical latent variable model were performed in accordance with the guidelines suggested by Sarstedt *et al.* (2019).

4.2.1 Quality management practices. Grounding on STS theoretical lens, QMPs improve quality performance more efficiently when it is introduced as an integrated whole thus embracing the dimensions of QMPs in a piecemeal approach may be failed to secure the effectiveness of QMPs. All dimensions of QMPs are interrelated, mutually supporting one another and can explicitly constitute a composite that is QMPs (Escrig-Tena *et al.*, 2011; Sim *et al.*, 2018). Therefore, for this study, QMPs were modeled as second-order construct, a composite formed by a linear combination of six distinct reflectively measured first-order constructs, namely, leadership (L), process management (PM), customer relationship management (CRM), supplier quality management (SQM), employee management and training (EMT) and lastly product design and control (PDC), as shown in Figure 1 (Sim *et al.*, 2018). The measurement model for first-order constructs with indicators that are reflective in nature is operationalized as a reflective measurement model. In the subsequent stage, these reflectively measured first-order constructs will form the second-order construct (QMPs) thus the measurement model for the second-order construct is operationalized as a formative measurement model.

4.2.2 Lean Six Sigma practices. For a reflective-formative type model, lower-order reflectively measured constructs do not share a common cause but rather form a general concept that fully mediates the influence on subsequent endogenous variables (Chin, 1998; as cited in Becker *et al.*, 2012). LSS practice is a managerial methodology that integrates the

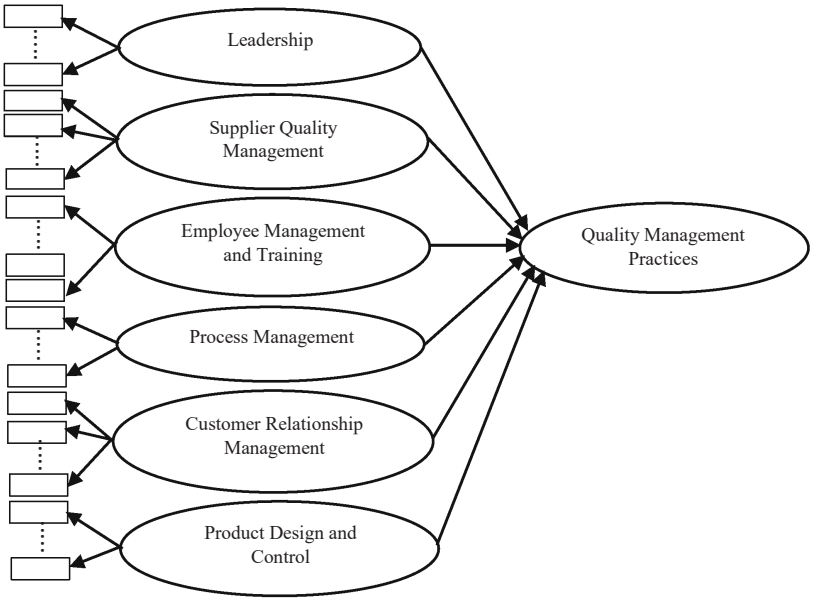


Figure 1.
Second-order multidimensional QMPs construct

concept of Lean and Six Sigma practices (Zhang *et al.*, 2012; Drohomeretski *et al.*, 2014; Niu and Fan, 2015; Pacheco *et al.*, 2015). In accordance with a recent study by Sim *et al.* (2022), LSS is conceptualized as a third-order construct formed (or caused) by two second-order constructs, namely, Lean and Six Sigma practices. Next, Lean manufacturing practices (second-order construct) are modeled as a composite of four distinct reflectively measured first-order constructs, namely, Just-in-Time (JIT), pull production system (PPS), flow management (FM) and setup time reduction (STR). In a similar vein, Six Sigma practices (second-order construct) are modeled as a composite formed by a linear combination of three distinct dimensions, namely, Six Sigma Role Structure, Six Sigma Structured Improvement Procedure and Six Sigma Focus on Metrics (Zu *et al.*, 2008; Parast, 2011; Shafer and Moeller, 2012; Patyal and Koilakuntla, 2015), as shown in Figure 2. In accordance with measurement theory, LSS practices are modeled as a third-order construct with two formatively specified items, namely, Lean and Six Sigma practices. Intrinsically, the measurement model for first-order constructs with indicators that are reflective in nature is operationalized as a reflective measurement model. Next, these reflectively measured first-order constructs will form the second-order constructs namely Lean and Six Sigma practices and these second-order constructs will form the third-order construct (LSS practices). Accordingly, the measurement model for second-order constructs and third-order construct are operationalized as a formative measurement model. As such, the estimation and testing of hierarchical latent variable model are performed in accordance with the guidelines suggested by Sarstedt *et al.* (2019). Last of all, all the assessment for this study is performed using SmartPLS 3.3.2 (Ringle *et al.*, 2015).

5. Findings

5.1 Assessment of measurement model

PLS-SEM algorithm estimates measurement model and structural model separately in which measurement model (outer model) assesses the relationship between the latent variables and its items, whereas the structural model (inner model) defines the relationship among the latent

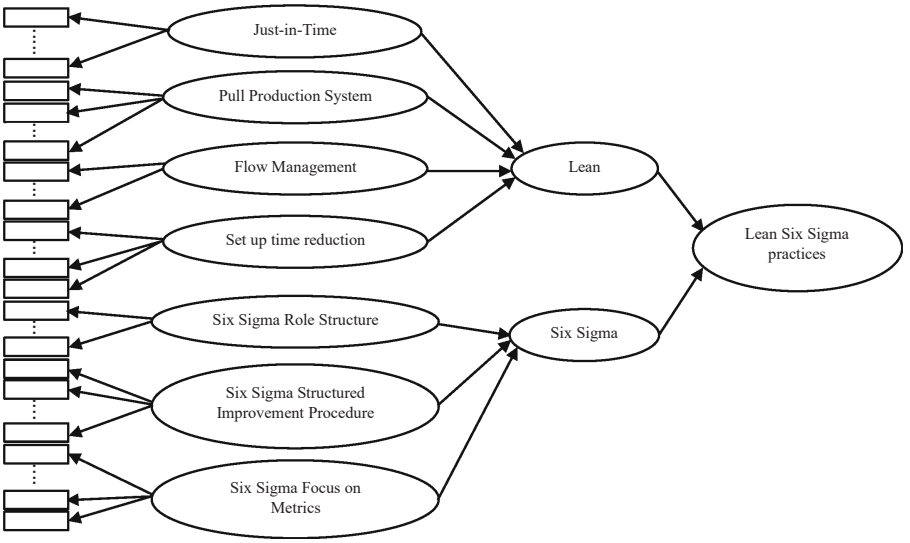


Figure 2.
Third-order multidimensional Lean Six Sigma practices

variables. A sound measurement theory is necessary to ensure the validity of PLS-SEM findings in the latter stage of assessing the structural relationships among the constructs (Jarvis *et al.*, 2003; Hair *et al.*, 2017). For specifying higher-order constructs, this study employed the disjoint two-stage approach (Sarstedt *et al.*, 2019). Following the guidelines proposed by Sarstedt *et al.* (2019), the psychometric properties of the first-order measurement model were first examined without the higher-order constructs and these first-order constructs are linked to all theoretically related constructs (Table 1).

5.1.1 Assessment of reflective measurement model. The assessment of the reflective measurement model begins with assessing the model's internal consistency reliability, convergent validity and discriminant validity to make certain that all the constructs are reliable and valid for the testing of structural relations (Hair *et al.*, 2011; Ramayah *et al.*, 2018). Results showed that the model demonstrated satisfactory internal consistency reliability and convergent validity with both composite reliability (CR) and average variance extracted (AVE) achieved the minimum threshold value of 0.8 (CR) and 0.5(AVE) (Hulland, 1999; Hair *et al.*, 2017). The model presented an adequate convergent validity with satisfactory AVE scores of greater than 0.5 for all constructs after the removal of several low loadings items; however, the loadings for several indicators that fall below the recommended value of 0.708 were retained given that the convergent validity of the constructs remained adequate, i.e. CRM4 (0.504), PM3 (0.592), FM6 (0.482), PPS2 (0.535), PPS3 (0.557) and SQM2 (0.59) (Hulland, 1999; Hair *et al.*, 2017). Subsequently, this study assessed the model's discriminant validity using heterotrait-monotrait ratio of correlation (HTMT) approach as suggested by Henseler *et al.* (2015). As shown in Table 2, the values of HTMT criterion are lower than the required threshold value of HTMT.85 (Kline, 2010) thus in referring to the HTMT criteria there were no discriminant validity issues for inter-construct correlations of 0.808 and lower. To further validate this finding, we also conduct the bootstrapped HTMT (Franke and Sarstedt, 2019) and found that they are statistically different from 1.

5.1.2 Assessment of formative measurement model. Consecutively, this study proceeds with the assessment of formative measurement models. The standardized LVS obtained in stage one will be computed as indicators for the second-order construct. Following the guidelines proposed by Sarstedt *et al.* (2019) and Ramayah *et al.* (2018), this paper assessed the collinearity issues of the formative measurement model and the significance and relevance of formative indicators. For this study, performing redundancy analysis to assess the convergent validity is not feasible given that no global item was developed beforehand to facilitate the analysis. Notwithstanding, results showed that the collinearity assessment yields a variance inflation factor (VIF) value of less than 3.3 for all the formative constructs thus suggesting that collinearity is not a concern in this study (Diamantopoulos and Siguaw, 2006). Sequentially, bootstrapping analysis is performed to assess the significance and relevance of relationships between the lower-order and higher-order components. As demonstrated in Table 3, the weight of indicators on their respective constructs appeared to be significant which is in support for the validity of formative second-order QMPs, Lean manufacturing practices and Six Sigma practices. Moreover, bootstrapping analysis showed that the correlation weights of Lean and Six Sigma practices on LSS practices also appeared to be significant, hence these results provided clear support for the validity of the third-order model LSS practices. Last of all, having ensured that the psychometric properties of higher-order models exhibit satisfactory at both item-level and higher-order level, this paper proceeds with the assessment of the structural model and examines the relevance of inner model relationships.

5.2 Assessment of structural model

Next, the assessment of the structural model involved five steps of procedure, namely, (1) assessment of collinearity, (2) assessment of significance and relevance of structural

Constructs	Indicator	Items	Loadings	CR	AVE
Customer Relationship Management (CRM)	CRM1	Company established close contact with their customers	0.852	0.861	0.561
	CRM2	Customers provide feedback on the quality and delivery performance	0.871		
	CRM3	Customer requirements are used as the basis for quality	0.739		
	CRM4	Company conducts market research to determine customers' needs and expectations	0.504		
	CRM5	Company collects information from customers to measure their satisfaction	0.721		
Employee Management and Training (EMT)	EMT1	Our firm forms teams to solve problems	0.745	0.906	0.582
	EMT2	Our firm gives feedback to employees on their quality performance	0.653		
	EMT3	Our employees are recognized for superior quality improvement	0.774		
	EMT5	Quality-related training is given to hourly workers in our firm	0.801		
	EMT6	Quality-related training is given to managers and supervisors in our firm	0.823		
	EMT7	Training is given in the "total quality concept" (i.e. philosophy of company-wide responsibility for quality) in our firm	0.777		
	EMT8	Training is given in the basic statistical techniques (such as histogram and control charts) in our firm	0.753		
Flow Management (FM)	FM1	Products are classified into groups with similar processing or routing requirements	0.757	0.883	0.564
	FM2	Equipment is grouped to produce a continuous flow of families of products	0.791		
	FM3	Families of products determine our factory layout	0.740		
	FM4	The cells/work centres/machines are arranged in relation to each other so that material movement, material handling and transit times are minimized	0.826		
	FM5	The shop-floor is laid out so that processes and machines are in close proximity to each other	0.848		
	FM6	We emphasize small lot sizes to increase manufacturing flexibility	0.482		
Six Sigma Focus on Metrics (FOM)	FOM1	Companies systematically follows a set of measures (such as defects per million opportunities, sigma level, process capability indices, defects per unit and yield) to evaluate process improvements	0.936	0.980	0.873
	FOM2	The measures for quality performance are connected with critical-to-quality (CTQ) characteristics	0.926		
	FOM3	Company sets strategic goals for quality improvement	0.960		

Table 1.
Assessment of measurement model

(*continued*)

Constructs	Indicator	Items	Loadings	CR	AVE
	FOM4	Company has a comprehensive goal-setting process for quality	0.931		
	FOM5	Quality goals are clearly communicated to employees	0.920		
	FOM6	Company's quality goals are clear and specific	0.946		
	FOM7	Company translates customers' needs and expectation into quality goals	0.922		
Just in Time (JIT)	JIT1	Our suppliers deliver materials/products in just-in-time basis	0.739	0.853	0.660
	JIT2	Our key suppliers are located in close proximity to our firm	0.832		
	JIT3	We receive products from suppliers in small lots with frequent deliveries	0.860		
Leadership (L)	L1	Top management (i.e. major department head) assumes responsibility for quality performance	0.827	0.953	0.772
	L2	Top management actively participates in the quality improvement process	0.895		
	L3	Top management is committed in pursuing long-term quality objectives	0.908		
	L4	Top management discussed and reviewed quality-related issues in firm's meetings	0.894		
	L5	Top management emphasized continuous improvement of quality in all work processes at various levels	0.917		
	L6	Priorities are given by top management in the allocation of sufficient resources and time for quality improvement initiatives	0.825		
Product Design and Control (PDC)	PDC1	Products designs are thoroughly reviewed before it is produced and marketed	0.88	0.939	0.720
	PDC2	Multiple departments (such as marketing, manufacturing and purchasing) coordinate in the product development process	0.719		
	PDC3	Manufacturing and quality people are involved in the product/service development process	0.856		
	PDC4	Quality of new product is emphasized in relation to cost or schedule objectives	0.779		
	PDC5	We design for manufacturability	0.909		
	PDC6	The clarity of product specifications and procedures are listed	0.928		
Process Management (PM)	PM1	Processes in our firm are designed to be "mistake-proof" to minimize the chances of errors	0.639	0.895	0.553
	PM3	We usually meet the production schedule every day	0.592		
	PM5	Our firm conducts preventive equipment maintenance	0.744		

(*continued*)

Table 1.

Constructs	Indicator	Items	Loadings	CR	AVE
	PM6	Clear work or process instructions are given to employees	0.846		
	PM7	Our firm's shop floors are well organized and clean	0.767		
	PM8	A large number of the equipment or processes on the shop floor are currently under statistical process control	0.782		
	PM9	We make extensive use of statistical techniques to reduce variance in processes	0.804		
Pull Production System (PPS)	PPS1	We use a "pull" production system in which items produced are driven by the demand from downstream (customer)	0.745	0.838	0.517
	PPS2	Production is "pulled" by the shipment of finished goods	0.535		
	PPS3	Production at workstations in "pulled" by the current demand of the next station	0.557		
	PPS4	We use kanban to authorize the production or material movement	0.803		
	PPS5	To authorize the order, we use a supplier kanban that rotates between factory and suppliers	0.889		
Quality Performance (QP)	QP1	The quality of our firm's products has been improved	0.776	0.917	0.650
	QP2	The process variability in our firm has decreased	0.797		
	QP3	The delivery of our products has improved	0.844		
	QP4	The percentage of scrap and rework in our firm has decreased	0.795		
	QP5	The product cycle time (from receipt of raw materials to shipment of finished products) in our firm has decreased	0.752		
	QP6	Customer satisfaction with the quality of our products has increased	0.866		
Six Sigma Structured Improvement Procedure (SIP)	SIP1	Continuous improvement projects are conducted by following a formalized procedure (i.e. DMAIC—Define, Measure, Analyse, Improve and Control)	0.914	0.966	0.825
	SIP2	Company adopts a structured approach to manage quality improvement activities	0.898		
	SIP3	Company adopts a formal planning process to decide the major quality improvement projects	0.938		
	SIP4	All improvement projects are reviewed regularly during the process	0.913		
	SIP5	Company keeps records related to each continuous improvement project that was being conducted	0.928		
	SIP6	Product design process follows a systematic procedure	0.856		

Table 1. (*continued*)

Constructs	Indicator	Items	Loadings	CR	AVE
Supplier Quality Management (SQM)	SQM1	Company established long-term relationships with suppliers	0.741	0.893	0.629
	SQM2	Company works in close collaboration with suppliers in product development and process improvement	0.59		
	SQM3	Suppliers are selected based on quality rather than price and delivery performance	0.826		
	SQM4	Company has systematic supplier rating system	0.876		
	SQM5	Suppliers are evaluated periodically to meet stricter quality specifications	0.895		
Six Sigma Role Structure (SRS)	SRS1	Black/green belt role structure (or equivalent structure) is used for continuous improvement	0.929	0.967	0.830
	SRS2	Black/green belt role structure (or equivalent structure) is used for preparing and deploying individual employees for continuous improvement programs	0.955		
	SRS3	In your firm, the members of quality improvement team have their roles and responsibilities specifically identified	0.819		
	SRS4	Black/green belt role structure (or equivalent structure) helps your firm to recognize the depth of employees' training and experience	0.959		
	SRS5	An employee's role in the black/green structure (or equivalent structure) is considered for compensation and promotion decisions	0.883		
	SRS6	Differentiated training are provided so that employees who have different roles in the black/green belt role structure (or equivalent structure) can obtain the necessary knowledge and skills to fulfil their job responsibilities	0.915		
Setup Time Reduction (STR)	STR1	Our employees practice to reduce the set-up time required	0.959	0.944	0.850
	STR2	We are working to lower setup times in our firm	0.921		
	STR3	We have low set up times of equipment in our firm	0.884		

Note(s): CR = Composite Reliability; AVE = Average Variance Extracted

Table 1.

relationship, (3) assessment of in-sample prediction (R^2), (4) assessment of effect size (f^2) and lastly (5) assessment of predictive relevance (PLSPredict) (Hair *et al.*, 2017; Ramayah *et al.*, 2018). As seen from Table 4, the collinearity assessment yields a VIF value which is lower than the violating value of 3.3 or 5 (Hair *et al.*, 2017) hence suggesting that the model has negligible multicollinearity issues (Hair *et al.*, 2011). Consecutively, this paper performed bootstrapping analysis (one-tailed test) executed at 1,000 subsamples to empirically substantiate the existence of the hypothesized relationship. For this study, the product indicator approach is employed to examine the influence of the interaction term QMPs*LSS

Table 2.
Assessment of discriminant validity

	CRM	EMT	FM	FOM	JIT	L	PDC	PM	PPS	QP	SIP	SQM	SRS	STR
CRM														
EMT	0.726													
FM	0.364	0.414												
FOM	0.330	0.395	0.116											
JIT	0.125	0.184	0.170	0.232										
L	0.600	0.628	0.364	0.332	0.068									
PDC	0.518	0.415	0.153	0.200	0.091	0.387								
PM	0.735	0.752	0.463	0.334	0.192	0.561	0.666							
PPS	0.229	0.190	0.274	0.097	0.382	0.090	0.334	0.336						
QP	0.522	0.574	0.374	0.173	0.241	0.503	0.272	0.571	0.317					
SIP	0.424	0.427	0.333	0.785	0.294	0.286	0.409	0.603	0.221	0.320				
SQM	0.808	0.587	0.383	0.234	0.125	0.594	0.435	0.802	0.234	0.557	0.358			
SRS	0.462	0.427	0.376	0.592	0.320	0.362	0.306	0.516	0.275	0.408	0.753	0.419		
STR	0.405	0.433	0.587	0.224	0.189	0.346	0.264	0.482	0.442	0.503	0.372	0.363	0.437	

Note(s): $HTMT_{0.85}$ (Kline, 2010)

	Weight	STDEV	*T* value	*P* values	VIF
Second-order measurement model assessment					
Customer Relationship and Management → QMPs	0.211	0.024	8.904	0.000	2.393
Employee Management and Training → QMPs	0.263	0.029	9.090	0.000	2.219
Flow Management → Lean	0.387	0.060	6.452	0.000	1.397
Just-in-Time → Lean	0.182	0.100	1.826	0.034	1.148
Leadership → QMPs	0.206	0.026	8.020	0.000	1.772
Process Management → QMPs	0.230	0.020	11.281	0.000	3.241
Product Design and Control → QMPs	0.142	0.032	4.373	0.000	1.664
Pull Production System → Lean	0.279	0.066	4.225	0.000	1.297
Quality Performance ← QP	1.000	0.000			1.000
SS Focus on Metric → Six Sigma Practices	0.232	0.065	3.589	0.000	2.306
SS Improvement Procedure → Six Sigma Practices	0.396	0.056	7.053	0.000	3.295
SS Role Structure → Six Sigma Practices	0.493	0.069	7.187	0.000	2.073
Setup Time Reduction → Lean	0.544	0.068	7.948	0.000	1.520
Supplier Quality Management → QMPs	0.202	0.020	10.331	0.000	2.411
Third-order measurement model assessment					
Lean → Lean Six Sigma Practices	0.688	0.080	8.647	0.000	1.216
QP ← Quality Performance	1.000	0.000			1.000
Six Sigma Practices → Lean Six Sigma Practices	0.492	0.075	6.554	0.000	1.216

Table 3. Assessment of second and third order formative measurement model

	Beta	STDEV	*T* value	*P* values	LLCI	ULCI	VIF	f^2	$R^2_{included}$	$R^2_{excluded}$	Q^2
Lean Six Sigma practices → Quality Performance	0.229	0.083	2.774	0.003	0.091	0.368	1.354	0.085	0.530		0.456
QMPs → Quality Performance	0.441	0.096	4.579	0.000	0.265	0.581	1.740	0.245		0.489	
QMPs*LSS → Quality Performance	−0.182	0.064	2.846	0.002	−0.295	−0.089	1.352	0.098			

Table 4. Assessment of structural and moderation model

on the relationship between QMPs and quality performance. For moderation analysis, the main effect model is first estimated without the interaction term and the result revealed that both QMPs ($\beta = 0.441$, $t = 4.579$, CI [0.265, 0.581]) and LSS practices ($\beta = 0.229$, $t = 2.774$, CI [0.091, 0.368]) have a significant and positive impact on quality performance. Subsequently, the interaction effect model is analyzed with the inclusion of the interaction term and the result revealed that the interaction between QMPs*LSS is negative ($\beta = -0.182$, $t = 2.846$, CI [−0.295, −0.089]) thus hypothesis H_1 is not supported. Gardner *et al.* (2017) implied that substituting effect occurs when both the predictor and moderator exert the same directional influence on the criterion, whereas the interaction effect showed the opposite sign. In line with the aforementioned, this paper argued that LSS practices served as a substitute in moderating the positive relationship between QMPs and quality performance in such a way that the relationship becomes stronger (weaker) as LSS practices decrease (increase) (Gardner *et al.*, 2017).

In moderation analysis, the changes of R^2 and effect size of interaction effect determined the degree of moderation. In PLS-SEM, the R^2 excluded value was attained when the interaction effect was omitted from the structural model and the R^2 included was attained when the interaction effect was included. As shown in Table 4, the R^2 for endogenous latent variable (quality performance) prior to the addition of interaction term (QMPs*LSS) is 0.489

and with the addition of the interaction term the R^2 value is 0.530. The R^2 change of 0.041 demonstrated that the addition of QMPs*LSS has resulted in 4.1% additional explained variance in quality performance. Furthermore, the result revealed that the computed effect size (f^2) for the interaction effect is 0.098 thus this can be concluded that the interaction effect of QMPs*LSS practices has a small effect on quality performance (Cohen, 1988). Next, the predictive relevance of the model is estimated using PLSPredict (Shmueli *et al.*, 2019). Results showed that the $Q^2_{predict}$ has a value larger than zero and that both the RMSE and MAE values from the PLS-SEM analysis are lower than the naïve LM benchmark for most of the indicators of quality performance (Table 5) indicating that the model has predictive ability.

In addition, the extent to which an interaction effect increases or decreases the association between QMPs and quality performance can be visualized via a two-way interaction plot. Henceforth, a graphical illustration of the moderation effect by dint of slope (interaction) plot is attached to provide further explanation on the size and nature of the significant interaction effect (Dawson, 2014; Hair *et al.*, 2017; Gardner *et al.*, 2017). Figure 3 illustrates the relationship between QMPs and quality performance at low and high levels of LSS practices. As shown in Figure 3, the directionality of coefficients for QMPs and LSS practices are the same hence the converging lines occur at the high value of QMPs. The statistically significant and negative interaction effect ($\beta = -0.182$) would imply that the relationship between QMPs and quality performance becomes weaker as LSS practices increase. In addition, the line labeled for low levels of LSS practices also appeared to have a steeper gradient as compared to high levels of

Table 5.
PLS predict

	PLS			LM		Difference	
	RMSE	MAE	Q^2_predict	RMSE	MAE	RMSE	MAE
QP1	0.635	0.44	0.147	0.661	0.454	−0.026	−0.014
QP2	0.775	0.614	0.132	0.786	0.632	−0.011	−0.018
QP3	0.676	0.498	0.219	0.683	0.517	−0.007	−0.019
QP4	0.854	0.623	0.13	0.854	0.621	0	0.002
QP5	0.919	0.705	0.103	0.936	0.719	−0.017	−0.014
QP6	0.75	0.552	0.215	0.746	0.56	0.004	−0.008

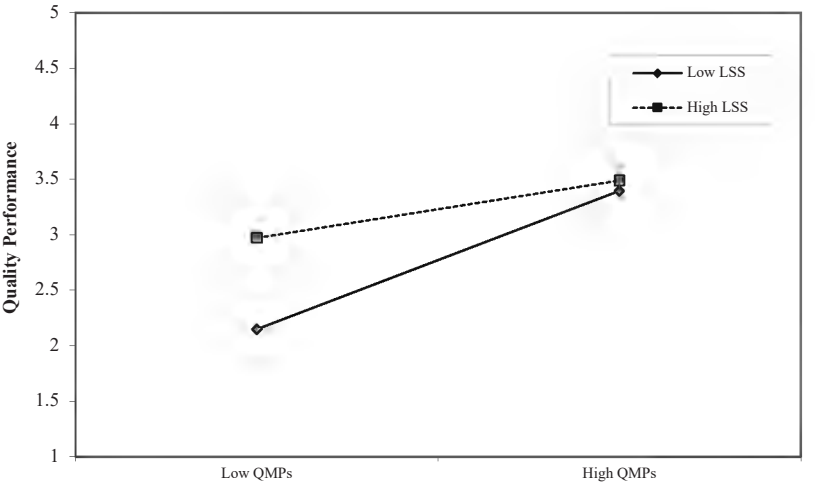


Figure 3.
Interaction plot for QMPs*LSS

LSS practices thus this would suggest that at a high level of LSS practices the relationship between QMPs and quality performance becomes weaker.

6. Discussion and conclusion

With the growing list of TQM companies setting their sights on LSS as a robust continuous process improvement methodology, this has triggered the need to further verify this issue empirically. An important contribution of this paper lies in the unfolding of the statistically significance and negative interaction effect of QMPs*LSS. Both QMPs and LSS practices have a significant and positive influence on quality performance, nevertheless, the negative coefficient of the interaction term QMPs*LSS suggests that at a high level of LSS practices the relationship between QMPs and quality performance becomes weaker. Seemingly, the result demonstrated that excessive emphasis placed on the implementation of LSS practices in the QM/TQM environment does not appear to have reflected in better quality performance. This finding is consistent with earlier studies which indicated that not all companies benefited from the LSS practices (Jeyaraman and Teo, 2010; Jones, 2014; Antony *et al.*, 2019) and the implementation of LSS practices are not always effective in the manufacturing settings (Lawless, 2016). The introductory of LSS practices in the TQM environment may trigger employees' resistance to change especially when their workload increases, job description changes, in addition to, the lack of the awareness on the benefits of deploying LSS practices. This finding is aligned with previous literature which claimed that excessive emphasis on LSS program might put pressure on employees' existing workloads which often diverts employees' attention away from performing at work (Detert *et al.*, 2000). In addition, the substituting effect of LSS practices maybe due to the initial resistance shown by both the middle-level management and employees resulting from the lack of training and insufficient knowledge to support the LSS project through to completion (Snee, 2010; Albliwi *et al.*, 2014; Bhat *et al.*, 2014; Antony *et al.*, 2019). Contrariwise, at a low level of LSS practices the relationship between QMPs and quality performance becomes stronger, hence, this would suggest that for TQM companies to benefit from LSS practices in attaining quality goals addressing necessary supporting procedures with the nature of the problem defining the selection of methodology would have been more effective instead of executing both methodologies in parallel.

With these insights, the practitioners are aware that direct implementation of LSS in any manufacturing company may result in failure due to insufficient knowledge of the statistical tools, lack of commitment from the top management, inadequate training, limited resources allocation and so forth (Albliwi *et al.*, 2014; Swarnakar *et al.*, 2020). The implementation of LSS practices required continuous training and development, commitment of employees, significant resources and knowledge to establish such a structure within an organization (Kumar and Bauer, 2010; Hill *et al.*, 2018). Hence, it is inevitably crucial for top management to allocate sufficient resources and equip the employees with the necessary skills and knowledge to overcome their resistance to change and be able to support the LSS project through to completion (Sim *et al.*, 2022). Failed execution of LSS practices often resulted in the loss of production efficiency, poorer quality performance and monetary losses (Chen *et al.*, 2010; Swarnakar *et al.*, 2020). Nevertheless, the authors believe that the proper execution of LSS practices in the TQM environment may exhibit an enormous potential for quality improvement. Hence, this paper encourages the use of LSS practices in a complementary fashion to support the QM processes in the MDM industry to attain optimum quality and speed. Besides, LSS Sigma practices are long-term strategies thus collecting data at a specific point in time were unable to provide accurate immediate short-run feedback on whether the quality improvement efforts are succeeding. On top, the implementation of LSS practices in the TQM environment is not without challenges especially when LSS methodologies remain

in the infancy stage in Malaysia (Habidin *et al.*, 2016). In brief, the findings of this paper will serve as a valuable implication for industry practitioners in providing them with a clearer managerial direction in incorporating LSS practices in the TQM environment to attain company's quality goal.

As any other study, this paper has its own limitations. First, this paper merely focused on Malaysian MDM industry, owing to this limitation, authors would like to recommend further research to be extended across different industries and different countries to generalize the findings. Moreover, the authors would also like to suggest the use of Importance and Performance Matrix analysis (IPMA) to identify the importance and performance of each construct which will provide a better insight for an industrial practitioner in prioritizing the construct that exhibit greater importance in improving the quality performance. Future studies may also examine the mediated moderation effect of *people capability* in the proposed research model seeing as the successful implementation of LSS practices is riding on the skills and competencies of employees to support the LSS project (Albliwi *et al.*, 2014; Antony *et al.*, 2019). Additionally, the findings of this paper revealed that the implementation of QMPs and LSS practices on a standalone basis has a significant positive impact on quality performance; however, the adoption of LSS practices in TQM environment do not improve the quality performance as anticipated hence further research can be conducted to address this discrepancy. Moreover, the authors would also like to suggest the use of a mixed method approach to investigate the organizational phenomena given that heavy reliance on a quantitative approach may have failed to address the existing issues faced by organizations. Furthermore, the lack of empirical research on LSS has suggested that this field of study remains relatively new; hence, further research on the current topic is, therefore, required. Ultimately, this study will serve as a basis for further research in this area.

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