# Implementing fast track surgery in hip and knee arthroplasty using the lean Six Sigma methodology

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## Abstract

**Purpose** – One of the biggest challenges in the health sector is that of costs compared to economic resources and the quality of services. Hospitals register a progressive increase in expenditure due to the aging of the population. In fact, hip and knee arthroplasty surgery are mainly due to primary osteoarthritis that affects the elderly population. This study was carried out with the aim of analysing the introduction of the fast track surgery protocol, through the lean Six Sigma, on patients undergoing knee and hip prosthetic replacement surgery. The goal was to improve the arthroplasty surgery process by reducing the average length of stay (LOA) and hospital costs

**Design/methodology/approach** – Lean Six Sigma was applied to evaluate the arthroplasty surgery process through the DMAIC cycle (define, measure, analyse, improve and control) and the lean tools (value stream map), adopted to analyse the new protocol and improve process performance. The dataset consisted of two samples of patients: 54 patients before the introduction of the protocol and 111 patients after the improvement. Clinical and

demographic variables were collected for each patient (gender, age, allergies, diabetes, cardiovascular diseases and American Society of Anaesthesiologists (ASA) score).

**Findings** – The results showed a 12.70% statistically significant decrease in LOS from an overall average of 8.72 to 7.61 days. Women patients without allergies, with a low ASA score not suffering from diabetes and cardiovascular disease showed a significant a reduction in hospital days with the implementation of the FTS protocol. Only the age variable was not statistically significant.

**Originality/value** – The introduction of the FTS in the orthopaedic field, analysed through the LSS, demonstrated to reduce LOS and, consequently, costs. For each individual patient, there was an economic saving of € 445.85. Since our study takes into consideration a dataset of 111 patients post-FTS, the overall economic saving brought by this study amounts to €49,489.35.

**Keywords** Six Sigma, Lean thinking, Arthroplasty, Public health, Clinical pathway

**Paper type** Research paper

## 1. Introduction

Millions of people undergo surgery every year worldwide; its aim is to promote patients' health, well-being and a better quality of life (Gheysari *et al.*, 2016). Italy is one of the first countries in Europe based on the number of hip and knee replacements as evidenced by the Superior Institute of Health, for the hip 38,498 operations were made (72.8% of cases undergo a total replacement, 22.1% partial replacements and 5.1% revisions), while for the knee 28,038 operations were made, (84.4% were total knee replacements and 15.6% single compartment). Both the hip and the knee cover about 90% of almost all cases; the primary cause that led to the intervention was primary osteoarthritis (OA) (Report RIAP 2018; ISS). OA is the most common form of joint disease and arises from a gradual degenerative change in the articulation structure. It is associated with any articulation in the body, but the most affected ones are the hip and knee; indeed, it has been calculated that about 251 million people suffer from knee OA worldwide. It obviously increases with age and with the constant rise of the aging in the global population and, consequently, the economic expense of the disease is also likely to increase (Kamaruzaman *et al.*, 2017).

In any case, surgery leads to psychological stress and has a great impact on patients and their families; thus, a large part of the hospital's capital is spent in operating rooms, and the 30.1% of the total healthcare costs are related to those of interventions (Ghardashi, 2007). Therefore, one of the major health challenges is the one of costs compared to economic resources and the quality of services. Tertiary hospitals have seen an incremental increase in spending due to the aging population. Hence, an intervention strategy could be the reduction of the length of stay (LOS) of patients in hospitals to ensure the sustainability of health systems; indeed, LOS is one of the key performance indicators used to establish hospital efficiency (Buttigieg *et al.*, 2018).

Mathematical and managerial tools strategies can help in reducing costs and in improving quality of healthcare services, from multi-criteria decision-making methods (Improta *et al.*, 2019a, b; Ricciardi *et al.*, 2020a; Sorrentino *et al.*, 2020; Trunfio *et al.*, 2020), to algorithms for biomedical data mining (Ricciardi *et al.*, 2019a, 2020b; D'Addio *et al.*, 2020; Romeo *et al.*, 2020) and analysis (Romeo *et al.*, 2014, 2018; Ricciardi *et al.*, 2020c; Improta *et al.*, 2020a), to novel process management and re-engineering techniques (Improta *et al.*, 2019c; Montella *et al.*, 2017; Converso *et al.*, 2015; Cesarelli *et al.*, 2020). Among the most common managerial techniques, the lean Six Sigma (LSS) methodology plays a considerable role (Improta *et al.*, 2017, 2018a). LSS is a management method aimed at improving performance based on the synergy of two tools: lean thinking and Six Sigma (Kawaguchi *et al.*, 2015).

As regards surgery, several interventional measures have been taken in recent years to improve patient recovery. Henrik Kehlet introduced enhanced recovery after surgery (ERAS), also known as fast track surgery (FTS), in the 1990s (Kehlet and Dahl, 2003). Over the past decade, this clinical pathway has been used extensively due to its significant benefits and safety. FTS is a multidisciplinary approach that aims to decrease the reaction to surgical

stress and organ dysfunction, thus promoting the postoperative recovery of patients by involving various medical specialties such as anaesthesia and management of preoperative fluids, nutrition, control optimal pain and rehabilitation (Ding *et al.*, 2017; Wilmore and Kehlet, 2001). The practical execution of FTS programs also provides for the formulation of a protocol that introduces actions to reduce morbidity and improve functional recovery, with subsequent reduction of LOS (Husted, 2012).

The literature shows that the FTS methodology was applied to patients undergoing hip replacement surgery due to osteoarthritis, making improvements in the reduction of LOS and in the management of care processes. Furthermore, this methodology was also successfully applied to patients undergoing knee replacement surgery.

Our study uses the LSS methodology to evaluate the implementation of the FTS protocol for hip and knee replacement prosthetic surgery processes. As a first step, we performed a qualitative analysis using the lean thinking tool. In particular, we used the basic stream map to identify waste from a qualitative point of view, while the Ishikawa diagram was used to identify the causes related to waste. Subsequently, with the Six Sigma methodology, a quantitative analysis was carried out to study the variation of LOS.

The contribution of our study was to combine data from patients undergoing hip and knee replacement surgery, which are the most performed orthopaedic surgeries in Italy, into a single study through the introduction of FTS validated with rigorous LSS analysis (Improta *et al.*, 2019d; Ricciardi *et al.*, 2020d). The new protocol is statistically analysed to evaluate the reduction of LOS, and the results obtained are presented in the appropriate section.

## 2. Literature review

FTS or ERAS have spread widely over the past 15 years and have proven effective in several procedures such as reducing LOS, morbidity and convalescence without increasing readmission rates or problems safely (Kehlet, 2008). The protocol consists of advanced perioperative medical management for total joint arthroplasty and was introduced to reduce mortality and functional discharge criteria with subsequent reduction in the LOS and high patient satisfaction (Husted, 2012). In recent years, the FTS protocol has been applied in several medical departments: in gastrointestinal surgery (Hu *et al.*, 2019; Liu *et al.*, 2016), in thoracic surgery (Che, 2020), hepatobiliary surgery (Kapritsou *et al.*, 2020), urology (Chen *et al.*, 2020) and other fields with a good clinical effect.

This protocol is also used in orthopaedic surgery; according to Hansen *et al.*, the FTS protocol was applied in total hip arthroplasty surgery with the reduction of post-operative LOS in the hospital, reducing convalescence and allowing faster functional recovery (Hansen, 2017); while in total knee replacement surgery, it was used to decrease readmission rates and possible complications (Pamilo *et al.*, 2018; Rodriguez-Merchan, 2015). The concept of FTS is to make use of the improvement of anaesthetic and analgesic techniques, the development of minimally invasive surgery and evidence-based perioperative care. It involves several items, beginning from the first medical visit before surgery to discharge. It is now well-established that pre-operative optimization can reduce the risk of complications and minimize the failure of the fast-track pathway (Rackwitz *et al.*, 2020). The pre-hospitalization represents a crucial phase of FTS protocol with the aim to optimize any organ dysfunction, address issues that may cause any potential risk and to optimize preoperative anaemia (Napier *et al.*, 2013).

In this work, the main idea is to find a solution that can improve quality and to reduce costs. In fact, in the healthcare context, the reduction of costs and the achievement of quality have always been achievable targets (Kenney, 2010; Van den Heuvel, 2006; Does *et al.*, 2010).

The lean thinking methodology was implemented by Toyota in the 1980s, revolutionizing the automotive industry as it turned out to be a methodical approach that can identify and eliminate waste (Womack *et al.*, 1990). The key principle of the lean thinking is to eliminate all

types of waste in the development of a higher operational production model with speed and efficiency, creating greater customer satisfaction. In particular, the wastes on which the methodology is based are seven:

(1) Overproduction: producing more than required;

(2) Inventory: extra conservation of material in all processes;

(3) Overprocessing: do more work;

(4) Motion: activity not essential for the purposes of the processes;

(5) Defects: revision and correction of defects;

(6) Waiting: activities awaiting completion and

(7) Transportation: unnecessary waste in the process of transporting equipment or materials (Alkinaidri and Alsulami, 2018; Nabiyouni and Franchetti, 2019).

However, by implementing lean in healthcare and reviewing the processes, it is possible to highlight an eighth waste, defined as none utilizes talent, i.e. when workers' time is not used to promote their creativity and talents in patient care (Catalyst, 2018).

Motorola, on the other hand, proposed Six Sigma in the mid-1980s as a methodology to reduce variability in the manufacturing process by improving process quality and reducing operating costs. One of the characterizing approaches to the improvement process is the DMAIC (define, measure, analyse, improve and control) cycle, which is based on five connected phases that lead to problem-solving and process improvement: in the define phase, the role of the team, the purpose of the project and the needs and expectations of the client are established; the measure phase includes the selection of the measurement factors to be improved and the provision of a structure for performance evaluation; the next step is based on defect determination and the priority to lead to advanced improvement using different analytical tools such as regression analysis, Ishikawa fishbone diagram, tree diagrams and brainstorming (analyse) (Improta et al., 2018a); the improve phase focuses on the use of experimentation and statistical techniques to generate possible improvements to reduce the quantity of quality problems and/or defects and the last phase ensures that the improvements are kept and performance monitoring underway (control phase) (Ansar et al., 2018).

Lean thinking and Six Sigma are two methodologies that complement each other: the former is a methodology that aims to eliminate waste by continuing to provide value to customers (Improta et al., 2018b; Cheung et al., 2016). Instead, the Six Sigma, as emerges from the literature data, reduces the number of defective products with a consequent increase in revenues and greater customer satisfaction (Kasemsap, 2016). The methodology allows to increase the time that care providers can give to patients, to reduce the time dedicated to paper material and to reduce the time people spend in waiting for treatment, complaints or calls (Improta et al., 2018b; Kasemsap, 2016).

The previous literature data showed that the LSS methodology through the DMAIC cycle was used for the introduction of the diagnostic therapeutic care path (DTAP) for patients with femur fracture (Ricciardi et al., 2019b): to study the efficacy of DTAP, two groups of patients were observed for 14 months (before and after the implementation of DTAP. Results showed a statistically significant reduction in LOS. In addition, DTAP was implemented to speed up the process of the surgical treatment for femoral fractures within 48 h of hospitalization (Improta et al., 2019e; Scala et al., 2020). Finally, LSS was used in hip and knee replacement prosthetic surgery processes, adopting pre-hospitalization as a corrective action to improve the quality of services provided to patients, clinical outcomes and reduce costs by reducing LOS. (Improta et al., 2015, 2017).

## 3. Materials and methods

Our center of orthopedics and traumatology provides regular inpatient treatment (elective or emergency), day-surgery inpatient treatment as well as outpatient services. The unit has 18 beds dedicated to regular admissions, six beds to day surgery activities and three operating rooms.

LSS was applied to evaluate the arthroplasty surgery process implemented by the direction of the department. In compliance with a typical LSS improvement process, the DMAIC cycle was adopted to thoroughly analyse the new protocol and to improve the performance of the process.

The data of patients in the present study were collected from printed medical records and digital information system database of the University Hospital "Federico II". A retrospective analysis was conducted on a sample of 54 patients undergoing arthroplasty replacement surgery before the new clinical protocol had been launched (from January 2016 to December 2016). To check the validity of the new clinical protocol pathway developed, information was collected on a sample of 111 patients operated during the months following the improvement (January 2017 to February 2019).

For each patient the following anamnestic, demographic and clinical variables were collected:

(1) Gender (man; woman);

(2) Age (<60; 60–75; >75);

(3) Presence of allergies, cardiovascular diseases and diabetes (yes; no);

(4) American Society of Anaesthesiologists (ASA) score (I–II; III–IV).

(5) Furthermore, the following dates were taken into consideration:

(6) Admission;

(7) Surgery and

(8) Discharge.

Statistical analyses, including Kolmogorov–Smirnov, Mann–Whitney, Kruskal Wallis and Chi square tests were performed using IBM SPSS Statistics version 25.

### 3.1 Define

The study was conducted by a multidisciplinary team composed of clinicians, biologists, economist and biomedical engineers with experience in health management. The purpose of this phase is to identify the problem and set up an execution team. First of all, a project charter was created where the details of the project are clearly and concisely shown (Table 1): problem statement, critical to quality (CTQ), goal statement, timeline and in and out of scope.

The objective of this paper is to evaluate the reduction of LOS, measured in days in a study combining prehospitalization and new action (FTS). The team also decided to perform a SIPOC (supplier, input, process, output and customer analysis), as shown in Table 1, to clarify the phases of the process and the project's purview (Breyfogle, 2003) (see Figure 1).

### 3.2 Measure

The purpose of the measure phase was to quantity process performance with the aim of implementing corrective measures to reduce the CTQ. In this phase, the data set was obtained from the sample consisting of 165 patients undergoing arthroplasty surgery: 54 patients are before the implementation of the FTS protocol in the period January 2016–December 2016 and 111 patients are after the implementation of the new protocol for establishing the improvement actions on LOS in the period January 2017–February 2019.

For each patient, all the acquired variables were analysed through descriptive statistics. Analyses were carried out to observe the influence of these variables on the average LOS. The Kolmogorov–Smirnov test was performed to study the normality of data distribution with an $\alpha$ significance level of 0.05 with a $p$-value of 0.014.

For a better visualization of the data, as per SS methodology, a bar chart has been created showing the distribution of the mean LOS for each variable (Figure 2).

### 3.3 Analyse

In this phase, according to lean thinking, the factors influencing the process were identified through a basic stream map, Figure 3. This tool shows the flow of the process from the patient's point of view which allows to identify value-added and non-value-added activities, waste,
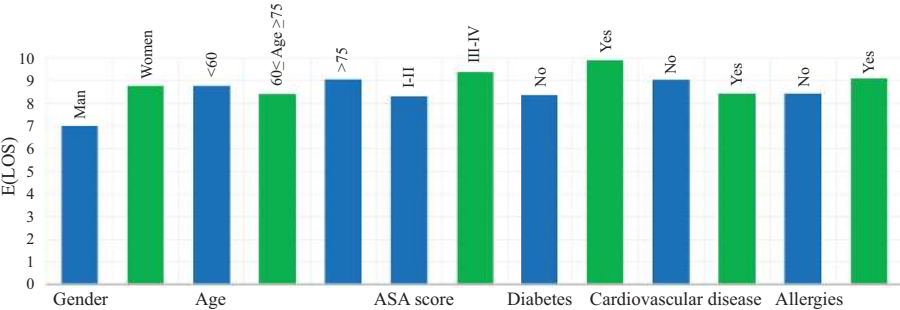
| Project charter | |
| --- | --- |
| Problem statement | Inappropriate prolongation of hospitalization for patients undergoing replacement surgery with a prosthetic hip and knee |
| Critical to quality | LOS measured in days |
| Goal statement | Implement corrective measures to reduce the CTQ |
| Timeline | Define: January 2016 |
| | Measure: December 2016 |
| | Analyse: December 2016 |
| | Improve: January 2017 |
| | Control: January 2017–February 2019 |
| In scope | Hip and knee replacement surgery |
| Out of scope | All other types of intervention in all other structures |

Table 1.
Project charter representing the main details of the research



Figure 1.
SIPOC to clarify the phases of the process



Figure 2.
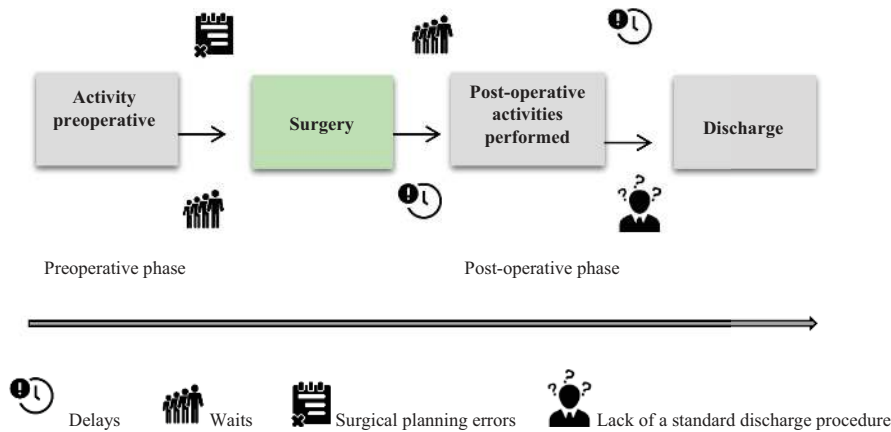Distribution of mean LOS for each variable and the relative categories

Figure 3.
Basic stream map
representing the
activities of the process

inefficiencies and delays. A statistical analysis was conducted to understand the variables that influence LOS quantitatively (Table 2). The independent variables used were: gender, age, allergies, cardiovascular diseases, diabetes and ASA score, while LOS was the dependent variable. The distribution of the data was verified with the Kolmogorov–Smirnov test ($p$-value 0.014), thus indicating a non-normal trend. Therefore, the Mann–Whitney test is used for dichotomous variables and the Kruskal–Wallis test for non-dichotomous ones (only age). Clearly, the results show that patient's gender influences LOS in the arthroplasty surgery process.

Furthermore, to investigate the root causes of the excessive duration of LOS in the process, a brainstorming session with all the team members and the clinical staff allowed us to find the potential causes:

(1) Patient,

(2) Healthcare staff,

(3) System and

(4) Process.

An Ishikawa fishbone diagram was developed to show the major causes with the relative secondary causes (Figure 4).

| Variable | Category | LOS [mean ± Dev. Std.] | $N$ | $p$-value |
|---|---|---|---|---|
| Gender | Man | 7.00 ± 1.51 | 15 | 0.002** |
|  | Women | 9.38 ± 3.01 | 39 |  |
| Age | <60 | 8.80 ± 3.17 | 20 | 0.454 |
|  | 60 ≤ Age ≤ 75 | 8.40 ± 2.87 | 20 |  |
|  | >75 | 9.07 ± 2.56 | 14 |  |
| Allergies | No | 8.45 ± 2.39 | 31 | 0.744 |
|  | Yes | 9.09 ± 3.44 | 23 |  |
| ASA score | Level I-II | 8.32 ± 2.00 | 34 | 0.338 |
|  | Level III-IV | 9.40 ± 3.91 | 20 |  |
| Diabetes | No | 8.38 ± 2.60 | 42 | 0.066 |
|  | Yes | 9.92 ± 3.53 | 12 |  |
| Cardiovascular diseases | No | 9.04 ± 3.25 | 25 | 0.868 |
|  | Yes | 8.45 ± 2.53 | 29 |  |

Table 2.
The potential variables
influencing LOS before
introducing the FTS
were studied through
univariate statistics

**Figure 4.**
Ishikawa fishbone diagram to evaluate main causes of excessive duration of LOS
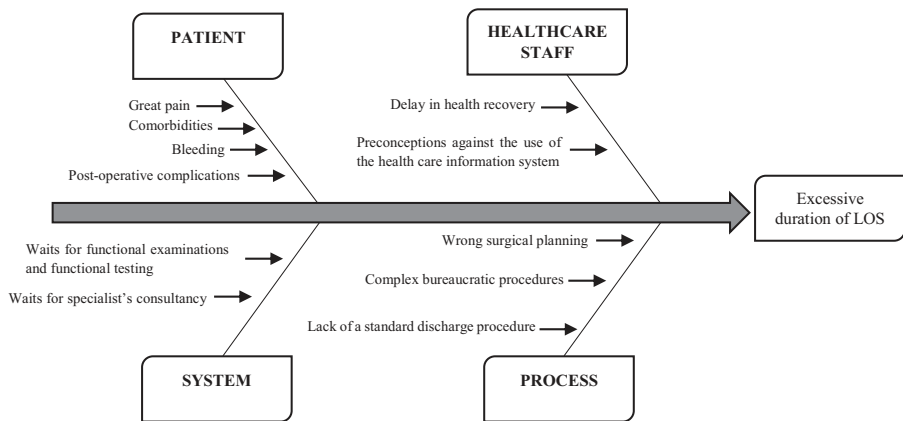
The causes represented in the Ishikawa diagram are related to the waste of lean thinking identified in the literature (Nabiyouni and Franchetti, 2019; Catalyst, 2018).

Among the main causes, the patients showed more inefficiencies: presence of pain, comorbidities, post-operative complications and bleeding. However, on the hospital side, within the system there were a greater wait in functional tests, examinations and specialist consultations. Instead, healthcare staff have shown delays in patient care, while the process is characterized by complex bureaucratic procedures and lack of a standard discharge procedure resulting in defects and over processing.

All of these causes lead to prolongation of LOS. Our work evaluates the theoretical contribution through a qualitative analysis, and in the following sections, the waste will be quantitatively measured with the LOS variable using the Six Sigma methodology.

Finally, some solutions have been found to solve the problems and are discussed in the improvement phase.

### 3.4 Improve

In the previous phase, the causes of the problem were identified, measured and analysed; then, the FTS protocol was implemented in 2017 at the Orthopaedics Department of University "Federico II" and is described below. It does not exclude any patient, regardless of age, comorbidity, ASA score or life situation. FTS combines various techniques used in the care of patients undergoing elective total hip and knee replacement surgery; the methods used include epidural or regional anaesthesia, minimally invasive surgical techniques, optimal pain and blood control, and aggressive postoperative rehabilitation, including early ambulation. The procedure involved a composite approach to achieve pain and haemostasis (bleeding/thromboembolism) control. The program in the operating set up comprised the administration of local (3 g /50 ml saline solution) tranexamic acid and local wound infiltration combined with anaesthetic agents. After the surgery, physiotherapy initiated within one day and lasts until discharge once or twice a day. Physiotherapy aims at improving the range of motion of the operated joint, strengthening the muscles and gaining a normal gait pattern with crutches. Multimodal intravenous and oral opioid-sparing analgesia was given to all patients, while opioid was included only on demand. Non-steroidal anti-inflammatory drugs and paracetamol were often concomitant drug combinations employed for multimodal analgesia. For thromboprophylaxis, low-molecular-weight heparin was provided once a day until 30 days after the operation.

Discharge procedures are performed according to the following criteria:

(1) Stable health conditions and satisfactory pain relief;

(2) Dry or almost dry wound and

(3) Capacity to independently dressing, going to the toilet and walking 30 m on crutches (and climbs stairs, only if able to walk on crutches).

Before introducing the FTS, no clinical pathway was adopted by the hospital for these patients. After the corrective action, the average LOS was reduced from 8.72 to 7.61 days, and the SD was reduced from 2.87 to 2.63 days (Table 3). Thus, we obtained a reduction of 12.70 % on average and 8.40 % in the SD for the patient LOS. Therefore, the implementation of the FTS protocol has proved to be a valid tool to solve the main causes identified. Patients gained greater benefit by recovering more quickly due to decreased morbidity, post-operative complications and bleeding. The healthcare staff through the FTS protocol has guaranteed an improvement in patient management by eliminating delays and inefficiencies. Finally, the standardized surgical procedure has improved the healthcare process by reducing patient expectations both from a bureaucratic point of view and in the delivery of the service.

*3.5 Control*
The aim of the control phase is to monitor the process, test the validity of the introduction of the FTS and plan revision actions to ensure a long-term result. To this regard, a comparative analysis was performed with the Mann Whitney test, taking into consideration a significance level $\alpha$ of 0.05 for LOS (Table 4) of patients undergoing arthroplasty surgery before and after the implementation of the protocol.

| LOS pre-improvement [mean ± Dev. Std.] | LOS post improvement [mean ± Dev. Std.] |
|---|---|
| 8.72 ± 2.87 | 7.61 ± 2.63 |

**Table 3.** Comparison before and after implementation

| Variables | Category | Pre-FTS [mean ± Dev. Std.] | Post FTS [mean ± Dev. Std.] | Difference of the mean [%] | $p$-value |
|---|---|---|---|---|---|
| All patients | | 8.72 ± 2.87 | 7.61 ± 2.63 | −12.70 | 0.008** |
| Gender | Man | 7.00 ± 1.51 | 7.58 ± 2.14 | 8.30 | 0.229 |
| | Women | 9.38 ± 3.01 | 8.15 ± 2.97 | −13.10 | <0.001*** |
| Age | <60 | 8.80 ± 3.17 | 8.54 ± 2.52 | −3.00 | 0.916 |
| | 60 ≤ Age ≥ 75 | 8.40 ± 2.87 | 7.60 ± 2.52 | −9.50 | 0.123 |
| | >75 | 9.07 ± 2.56 | 8.27 ± 3.33 | −8.80 | 0.071 |
| Allergies | No | 8.45 ± 2.39 | 7.83 ± 2.74 | −7.30 | 0.042* |
| | Yes | 9.09 ± 3.44 | 8.28 ± 2.77 | −8.90 | 0.115 |
| ASA score | Level I-II | 8.32 ± 2.00 | 7.72 ± 2.17 | −7.20 | 0.023* |
| | Level III-IV | 9.40 ± 3.91 | 8.67 ± 3.84 | −7.80 | 0.211 |
| Diabetes | No | 8.38 ± 2.60 | 7.71 ± 2.44 | −8.00 | 0.035* |
| | Yes | 9.92 ± 3.53 | 9.42 ± 3.78 | −5.00 | 0.212 |
| Cardiovascular diseases | No | 9.04 ± 3.25 | 7.52 ± 2.68 | −16.80 | 0.002** |
| | Yes | 8.45 ± 2.53 | 8.60 ± 2.74 | 1.80 | 0.828 |

**Table 4.** Statistical analysis of LOS related to each variable and category. *Significant at 0.05

In addition, a comparative statistical analysis was also performed for the clinical and demographic variables using the $\chi^2$ test with a significance level $\alpha$ of 0.05 to find significant differences between the frequencies of the categories of the two groups (Table 4).

Thanks to the use of the LSS methodology, it is possible to define a control plan to ensure improvements and long-term sustainability of the results. Therefore, based on previous studies, the following actions have been planned:

(1) Periodic checks to evaluate the implementation process, forecast of actions in case of problems highlighted during implementation and planning of actions to improve it.

(2) Internal audit to verify the implemented solutions and control mechanisms.

(3) Periodic updating of the control plan by the team and use of visual management tools to verify future developments.

Finally, for a graphic representation of the performance of the introduction of the FTS protocol, the run charts were created before and after implementation (Figure 5), which clearly shows the reduction of our CTQ.

## 4. Results
In the results section, the analysed data showed a non-normal distribution, so Mann Whitney's test was performed to compare pre-FTS and post-FTS LOS for each variable and related category. In Table 4, in the first period, an average of 8.72 days was recorded with a
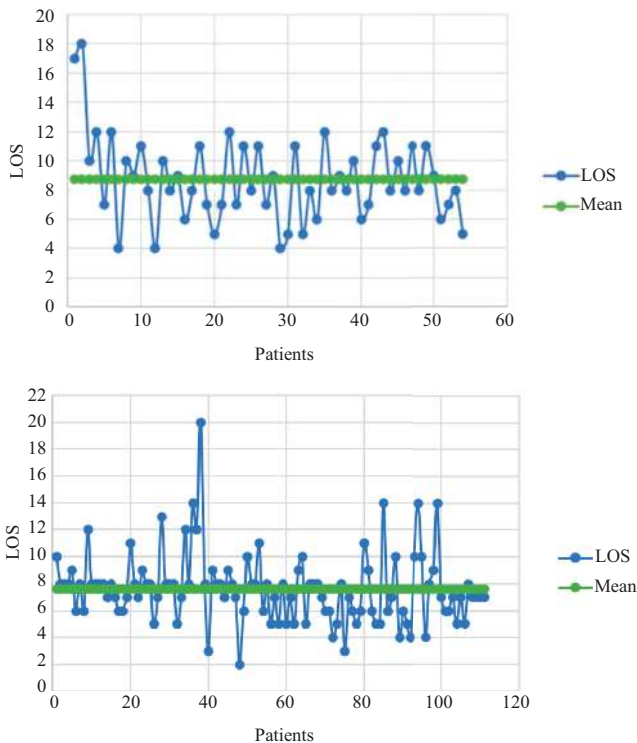


**Figure 5.**
Run charts before and
after implementation

SD of 2.87 days for patients not undergoing FTS from January 2016 to December 2016, while for post-FTS patients LOS was reduced by 12.70% from a mean of 8.72 to 7.61 days. Overall, the reduction in LOS was statistically significant ($p$-value 0.008).

Significant results were obtained for the variables: gender and in particularly for woman ($p$-value < 0.001), patients with low ASA score ($p$-value = 0.023) and patients without allergies ($p$-value = 0.042), diabetes ($p$-value = 0.035) and cardiovascular disease ($p$-value = 0.002). Indeed, women, patients without allergies, with a low ASA score meaning with a good general status of health, not suffering from diabetes and cardiovascular disease showed a reduction in hospital days with the implementation of the FTS protocol.

Furthermore, some groups of patients showed a good reduction in LOS in terms of difference of the mean without obtaining a significant result: patients with age between 60 and 75 years ($-9.5\%$) and greater than 75 years ($-8.80\%$), patients with allergies ($-8.90\%$) and patients with a high ASA score ($-7.80\%$) meaning with a worse status of health.

Finally, a demographic study was performed to find significant differences in frequency between the groups analysed using the $\chi^2$ test (Table 5). Except of the gender and diabetes variables, there were statistically significant differences between the groups analysed according to age, allergies, ASA score and cardiovascular disease ($p$-values < 0.05).

## 5. Discussion and conclusion

It has been reported that patients undergoing fast-track TKA recover better after general anaesthesia than after spinal anaesthesia, and that fast-track rehabilitation reduces the consumption of analgesic drugs and LOS. Preoperative anemia in fast-track TKA is associated with an increased risk of receiving transfusion during admission, increased risk of readmission within 90 days from the procedure and increased risk of LOS of more than five days (Rodriguez-Merchan, 2015). In this research, we proceeded with the application of the LSS methodology through the DMAIC cycle with the aim of improving the management of patients undergoing arthroplasty surgery by examining the post-operative phase with the introduction of a FTS protocol as a corrective action. The clinical benefit we were looking for was to allow patients to achieve better medical conditions and receive greater pain relief with a reduction of LOS.

Previous work has achieved satisfactory results in reducing LOS prolongation by improving the efficiency and effectiveness of arthroplasty processes by introducing the FTS protocol through LSS. Improta et al. (2019d) applied the FTS protocol in patients undergoing hip replacement surgery by reducing LOS from 10.66 to 7.8 days Ricciardi et al. (2020d)

| Variables | Category | Pre-FTS [N] | Post FTS [N] | $p$-value |
|---|---|---|---|---|
| Gender | Man | 15 | 35 | 0.623 |
| | Women | 39 | 76 | |
| Age | <60 | 20 | 17 | 0.003** |
| | $60 \leq$ Age $\geq 75$ | 20 | 68 | |
| | >75 | 14 | 26 | |
| Allergies | No | 31 | 81 | 0.045* |
| | Yes | 23 | 30 | |
| ASA score | Level I-II | 34 | 86 | 0.049* |
| | Level III-IV | 20 | 25 | |
| Diabetes | No | 42 | 97 | 0.112 |
| | Yes | 12 | 14 | |
| Cardiovascular diseases | No | 25 | 70 | 0.041* |
| | Yes | 29 | 41 | |

Table 5.
Demographic study performed through chi square Test.
*Significant at 0.05

introduced the FTS protocol in patients undergoing knee replacement surgery by reducing LOS from 8.34 to 6.68 days. In this study, a greater follow-up has been achieved guaranteeing long-run results, as per LSS methodology.

In patients undergoing hip arthroplasty, the FTS protocol was applied in the post-operative phase, reducing the mean LOS from 10.66 to 7.8 days ($-26.8\%$), while in patients undergoing knee arthroplasty, the LOS mean was reduced from 8.34 to 6.68 days ($-19.9\%$) (Wilmore and Kehlet, 2001; Husted, 2012). The results of our study showed, despite combining total hip and knee replacement surgery and enlarging the number of patients analysed, a reduction in LOS of 12.70% from an overall mean of 8.72 to 7.61 days (Table 4).

Significant results were obtained for the following variables: gender, allergies, ASA score, diabetes and cardiovascular disease; in particular, greater significance was demonstrated by the following categories: women, patients without allergies, with a low ASA score, not suffering from diabetes and cardiovascular disease. Then, a demographic study was conducted to find significant differences between the groups analysed using the chi-square test. Except of the gender and diabetes variables, there were significant differences between the groups analysed (Table 5). The presence of greater number of older people in the post-improvement group should lead to an increase of LOS in such group of patients; nevertheless, the post-improvement group experience an overall reduced LOS as regards both all patients and older patients (Tables 4 and 5). Therefore, the introduction of the FTS protocol has brought benefits both in patient management and in the hospital setting. These results are in line with the recent literature in which elderly patients and patients with high number of comorbidities would benefit more from rapid recovery protocols (Starks *et al.*, 2014; Jørgensen and Kehlet, 2013; Jørgensen *et al.*, 2015).

Furthermore, there is growing evidence of a reduction of specific complications in fast track total hip and knee osteoarthritis, such as the risk of thromboembolic complications, myocardial infarction, bleeding complications and cardiac arrest (Jørgensen *et al.*, 2013; Belmont *et al.*, 2014). Indeed, age, sex, marital status, co-morbidity, preoperative use of walking aids, pre- and post-operative haemoglobin levels, the need for blood transfusion, ASA score and time between surgery and mobilization were all found to influence post-operative outcome in general, and LOS and patient satisfaction in particular (Husted *et al.*, 2008).

During the study, the team faced some challenges for achieving better success. The data collection phase was not immediate because the information was collected from non-computerized medical records as the healthcare staff did not use to employ computerized systems. In addition, the team encountered difficulties in the implementation phase of the FTS protocol to support healthcare staff in implementing the managerial solutions defined by the study.

Nevertheless, the team succeeded in its goal; indeed, our study highlights the efficacy of improving pre-hospitalization phase to reduce post-operative LOS. The reduction of LOS is strictly correlated to the lower incidence of post-operative complication in patients included in FTS group than patients treated traditionally.

Although there is a reduction of 1.09 days, the significant impact on healthcare spending is highlighted with an improvement in healthcare management. Finally, it is important to introduce qualitative methodologies in health to try to face the economic problems that characterize this sector since the consumption of health resources is a central issue in many political and social debates (Improta *et al.*, 2020b).

This paper demonstrates the validity of the LSS methodology in the healthcare to reduce LOS and, consequently, costs. Indeed, through the introduction of the FTS protocol, patients can experience a faster recovery and reduce their permanence in the hospital. The pre-hospitalization represents a crucial phase of FTS protocol and for this reason should be implemented with the aim to reduce the impact of patient's risk factors on post-operative recovery.

There is no particular requirement for other researchers to introduce in their clinical settings the FTS since it does no distinction based on age, gender, ASA score, comorbidity or life situation. The only suggestion can be to implement this clinical pathway after having already introduced the pre-hospitalization in the hospital or health facility; the combination of FTS and pre-hospitalization will maximize its impact on costs and LOS.

Therefore, the benefits obtained from this research address both the managerial needs of the hospitals and the patients. A limitation of this work could be to expand the study variables to have a more detailed analysis of the influence on LOS. Future developments will be to examine patients' follow-up to improve the treatment process and expand the study variables (obesity, cardiopulmonary disease, smoking, alcohol, etc.) to have more detailed analysis of the influence on LOS. In addition, it would be important to study the mortality, morbidity and functional recovery of patients undergoing arthroplasty surgery. In conclusion, this study confirms the finding of many previous reports: that FTS reduces the LOS after TKA and THA and also the cost of both procedures.

### 5.1 Practical implications and future developments

Implementing the FTS protocol through these management methodologies has practical implications. This work confirmed once again that the LSS approach can effectively reduce costs. In fact, according to "DCA 32/2013 - Tariffe per la remunerazione dell'assistenza in regime di ricovero per acuti in Regione Campania"1 to replace major joints or reimplantation of the lower limbs (hip and knee) for ordinary hospitalizations with a hospital stay longer than one day and within the threshold (22 days), the daily cost of hospitalization amounts to € 401.68 per single patient. Before the introduction of the FTS, the cost of a single hospitalization was equal to € 3,502.65 (with the average LOS pre-FTS); after the implementation of the FTS protocol, the cost of a single hospitalization was € 3,056.18 (with the post-FTS LOS average). Therefore, for each individual patient there was an economic saving of € 445.85. Since our study takes into consideration a dataset of 111 patients post-FTS, the overall economic saving brought by this study amounts to €49,489.35.

Finally, this approach is clearly useful for society considering the benefits for hospitals and patients. Certainly, these results have a positive impact in the context in which they have been applied.

### Abbreviation

| | |
|---|---|
| ASA | American Society of Anaesthesiologists |
| CTQ | Critical to quality |
| DMAIC | Define, measure, analyse, improve and control |
| DTAP | Diagnostic Therapeutic Care Path |
| FTS | Fast track surgery |
| LOS | Length of stay |
| LSS | Lean Six Sigma |
| UOC | Complex operative unit |

### Note

1. www.soresa.it/pa/Contenuti/Flussi%20Sanitari/SDO/Specifiche%20funzionali/tariffe_ricoveri_2014.pdf

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