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ORIGINAL ARTICLE • SPINE - BIOMATERIALS

# Single-use versus reusable medical devices in spinal fusion surgery: a hospital micro-costing analysis

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## Abstract

**Purpose** Healthcare facilities could minimize the cost of surgical instrument and implant processing by using single-use devices. The main objective was to prospectively compare the total cost of a single-use and reusable device used in short lumbar spine fusion.

**Methods** A 1-year, single-centre, prospective study was performed on patients requiring a one- or two-level lumbar arthrodesis. Patients were randomized in two groups treated with either reusable or single-use device. A cost minimization analysis was performed using a micro-costing approach from a hospital perspective. Every step of the preparation process was timed and costed based on hourly wages of hospital employees, cleaning supplies and hospital waste costs.

**Results** Forty cases were evaluated. No significant difference in operation time was noted (reusable 176.1 ± 68.4 min; single use 190.4 ± 71.7 min; $p = 0.569$). Mean processing time for single-use devices was lower than for reusable devices (33 min vs. 176 min) representing a cost of 14€ versus 58€ ($p < 0.05$). Pre-/post-sterilization and spinal set recomposing steps were the most time-consuming in reusable device group. A total cost saving of 181€ per intervention resulted from the use and processing of the single-use device considering an additional sterilization cost of 137€ with the reusable device. The weight of the reusable device was 42 kg for three containers and 1.2 kg for the single-use device.

**Conclusions** Owing to the absence of re-sterilization, single-use devices in one- and two-level lumbar fusion allow significant money and time savings. They may also avoid delaying surgery in case of reusable device unavailability.

**Keywords** Single-use medical devices · Lumbar arthrodesis · Micro-costing analysis · Cost minimization analysis · Minimally invasive spine surgery

## Introduction

Lumbar spine fusion is performed on a regular basis by spine surgeons. The procedure requires a substantial number of instruments and implants which are delivered by the sterile processing department (SPD) to the operating theatre (OT). Cleaning and sterilizing reusable instruments represent a significant element of the total cost of a surgery [1–5]. SPD is one part of healthcare facility that may improve its internal management and progress towards more efficient resource consumption. Since there is no reprocessing after its use, single-use device might be a sustainable solution for hospital with a positive economic and organizational impact on SPD [6, 7]. Most studies comparing single-use and reusable device cost-effectiveness were on endoscopic instruments and led to mixed results [3, 8–10]. In the orthopaedic surgery field, literature focused mainly on single-use cutting blocks for arthroplasty [6, 7, 11, 12]. There is no randomized study comparing single-use versus reusable devices in spine surgery.

The main objective of this study was to prospectively compare the total cost of a single-use and reusable device used in short lumbar spine fusion.

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## Materials and methods

### Population

We conducted a prospective, randomized, single-centre study in the orthopaedic and spinal unit of our university hospital from May 2014 to April 2015. Inclusion criteria were patients between 18 and 80 years old requiring one- or two-level lumbar spinal fusion surgery (open or minimally invasive) for degenerative disc disease, spondylolisthesis (degenerative and isthmic), degenerative scoliosis and canal stenosis. Exclusion criteria were any physiological condition preventing optimal surgery (allergic reaction, fever, obesity, maternity, mental illness, osteoporosis), surgery not requiring bone fusion or for which a combination of different implants was anticipated, trauma and tumour cases since those cases were often treated emergently outside hours. An informed consent was obtained from patients included in the study. Ethics approval was obtained from the local institutional review board.

Patients were randomized to either single-use or reusable device before intervention. Planned sample size was 40 patients. Patients were submitted to the same care protocols pre-, intra- and postoperatively and followed up for at least 1 year.

### Surgical sets and implants

In the reusable device group, the CD Horizon® Legacy™ Spinal System and Capstone® cage (Medtronic©) was used and contained spinal instruments specific to spine surgery made of stainless steel. Only implants were invoiced; company did not charge for instruments and repairs. Set consists of three boxes containing instruments and various sized pedicle screws. Cages come in separate packages.

In the single-use device group, the sterile ready-to-use SteriSpine™ PS and LC (Safe Orthopaedics®) device made of polyacrylamide was used. Fusion surgery with single-use device follows the same steps as with reusable device. Single-use implants and instrumentation are delivered in multiple traceable kits (Fig. 1). One box contains instruments for lumbar interbody cage (curette, shaver, spreader, trials, cage holder). One box contains instruments for open and/or minimally invasive posterior fusion (pedicle awl, tap, rod holder, screw driver, etc.). Single-use set is modular with one instrument serving for different steps of the procedure (same handle has straight curette at on tip and curved curette at the other) (Fig. 1). For instance, scrub nurse may need to connect different shaver sizes to the same handle throughout the disc space preparation. One box contains two sterile rods. One box contains two preloaded sterile pedicle screws. Hospital was not charged for single-use instruments but only for implants. In case of breakage, instruments were replaced without added costs.

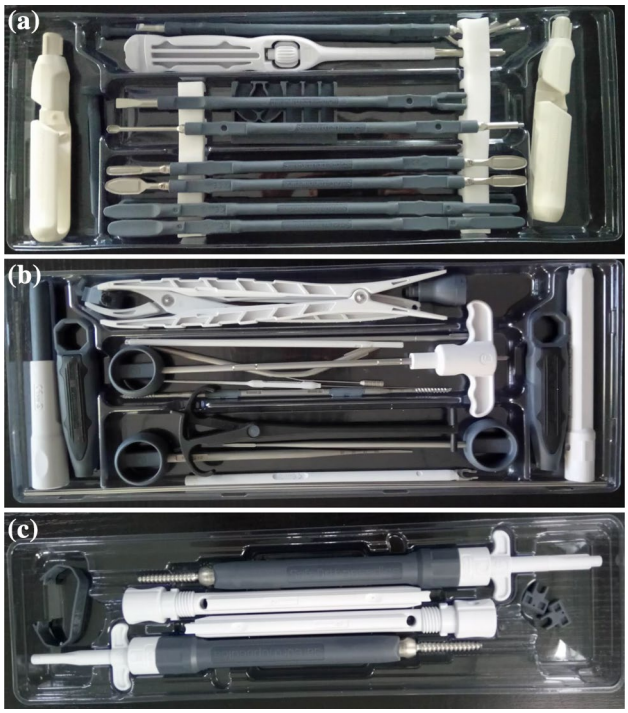


**Fig. 1** Single-use spinal kit SteriSpine™ PS and LC (Safe Orthopaedics®). **a** Instruments for lumbar interbody cage (curettes, shavers, trials, cage holder, etc.); **b** instruments for pedicle screws and rods insertion (pedicle awl, tap, rod holder, screw driver, etc.); **c** two preloaded sterile pedicle screws

Reusable and single-use device purchase costs were identical since it is a fixed cost negotiated between spinal implant companies and our National Health System.

### Data

A micro-costing analysis was performed according to the difference in processing between single-use and reusable devices [4]. Duration of each step of the processing was measured with a chronometer by three observers not involved in patients' care.

Reusable device processing was composed of seven steps: (1) manual pre-disinfection, (2) transport from operating room to sterilizing service; (3) washing instruments in automatized washing machine, (4) reusable instrument set and non-sterile implants (NSI) assembling, (5) sterilization, (6) transport to storage room, (7) transport to operating room and (8) instrument set preparation. Ordering NSI and reusable devices unpacking were considered negligible steps

mainly dependent on device renewal frequency and being just a part of a longer ordering to the company.

Single-use device processing was composed of five steps: (1) instrument set ordering, (2) instruments reception and transport to storage room, (3) transport from storage room to operating room, (4) instrument set preparation and (5) waste management.

Each step was valued taking into consideration salary of the staff involved, costs of various consumables and hospital waste. Mean operation duration, intra- and postoperative complications and length of stay were recorded in each group. Weight of handled instruments and any case of instrument renewal were evaluated. Depreciation cost of sterilization unit and infrastructures (operating theatre, pharmacy, logistics unit) was not analysed.

Since it was a micro-costing analysis, the primary outcome was the mean cost of the overall procedure for single-use and reusable device.

### Statistics

A Microsoft Excel database was established and used to record and analyse all data. Means, standard deviations, frequencies and percentages were used to descriptively summarize patients' demographics, costs and durations. Results were analysed using the statistical nonparametric Mann and Whitney *U* test. Significance was defined as a $p$ value of $<0.05$.

## Results

Forty patients were included in the study with 20 patients in reusable and single-use group (Table 1). Mean age was, respectively, 64.2 and 62.5 years ($p=0.68$). Most patients in each group presented with both lumbar and radicular symptoms and had similar imaging findings. No patients were lost to follow-up.

Overall, open and minimally invasive approaches were performed equally in each group (Table 2). A cage was required in, respectively, 90% and 95% of the cases. There was no difference in mean operating duration between

**Table 2** Surgical characteristics of the patients in the reusable and single-use group

| Characteristic | Reusable $N=20$ (%) | Single-use $N=20$ (%) |
|---|---|---|
| Approach | | |
| Open | 12 (60) | 10 (50) |
| Minimally invasive | 8 (40) | 10 (50) |
| Fusion | | |
| Cage | 18 (90) | 19 (95) |
| One-level arthrodesis | 13 (65) | 14 (70) |
| Two-level arthrodesis | 7 (35) | 6 (30) |
| Laminectomy | 12 (60) | 8 (40) |
| Operating duration (min) | 176 ± 68 | 190 ± 71 |
| Intraoperative complication | | |
| | 3 dural tear<br>1 blood loss > 500 mL | 1 dural tear |

**Table 1** Preoperative characteristics of the patients in the reusable and single-use group

| Characteristic | Reusable $N=20$ (%) | Single-use $N=20$ (%) |
|---|---|---|
| Gender | | |
| Male | 8 (40) | 11(55) |
| Female | 12 (60) | 9 (45) |
| Age (years) | 64.2 ± 12.8 (40–82) | 62.5 ± 11.2 (43–77) |
| Previous spine surgery | 5 (25) | 2 (10) |
| Symptoms | | |
| Back pain | 14 (70) | 15 (75) |
| Radicular pain | 15 (75) | 16 (80) |
| Leg weaknesses/neurological deficit | 13 (65) | 9 (45) |
| Imaging findings | | |
| Degenerative disc disease | 4 (20) | 8 (40) |
| Spinal canal stenosis | 11 (55) | 7 (35) |
| Degenerative spondylolisthesis | 9 (45) | 10 (50) |
| Isthmic spondylolisthesis | 2 (10) | 3 (15) |
| Degenerative scoliosis | 2 (10) | 0 |

**Table 3** Times and costs of processing steps in the reusable device group

| Step | Mean time in minutes (range) | Mean cost in euros (range) |
|---|---|---|
| Pre-disinfection | 27.5 (12.0–44.0) | 9.02 (4.56–15.70) |
| Transport from operating room to sterile processing department | 3.7 (2.0–6.1) | 1.16 (0.58–1.88) |
| Instrument assembling | 73.7 (35–135) | 23.90 (10.18–69.8) |
| Sterilization step | 52.4 (30.2–81.0) | 16.32 (9.87–24.66) |
| Order reception | 5.7 (2.9–24.0) | 2.02 (1.00–8.20) |
| Transport to operating theatre | 1.9 (0.2–3.5) | 0.82 (0.09–1.53) |
| Instrument set preparation | 11.5 (3.2–30.4) | 5.06 (1.39–13.32) |
| Total | 176.4 (109.4–248.4) | 58.30 (38.32–101.50) |

**Table 4** Times and costs of processing steps in the single-use group

| Step | Mean time in minutes (range) | Mean cost in euros (range) |
|---|---|---|
| Single-use device ordering | 10.4 (7.6–16.4) | 3.20 (2.22–4.77) |
| Order reception | 4.7 (2.5–9.1) | 1.79 (0.84–3.99) |
| Transport to operating theatre | 1.2 (0.4–3.0) | 0.53 (0.17–1.31) |
| Set preparation | 16.7 (5.5–42.0) | 7.30 (2.42–18.40) |
| General/infectious clinical waste | NA | 1.37 (0–2.66) |
| Total | 33.0 (22.2–59.4) | 14.19 (8.61–26.18) |

reusable and single-use device ($p = 0.569$). Instrument breakage (handle) occurred in four cases with single-use instruments with no consequences on surgical outcomes.

There was no difference in length of stay between reusable and single-use group ($7.1 \pm 1.7$ vs. $8.1 \pm 4.4$, $p = 0.98$). Postoperatively in reusable group, we reported one persistent radiculalgia, one leg motor deficit with partial recovery and one transient sensory deficit. Two patients required revision, one for CSF leak at 2 weeks and the other for L5/S1 pseudarthrosis at 1 year. There was no difference in length of stay between reusable and single-use groups ($7.1 \pm 1.7$ vs. $8.1 \pm 4.4$, $p = 0.98$). In the single-use group, we reported two persistent radiculalgia, two transient leg motor deficits and one transient sensory deficit. Two patients required emergent epidural haematoma drainage within a week but had no sequelae.

In the reusable group, mean perioperative processing time recorded in the reusable device group was 176.4 min (Table 3). Pre-disinfection (27.5 min), instrument assembling (73.7 min) and sterilization (52.4 min) accounted for 87% of the processing time. The time of order reception, transport from SPD to OT and return was only 6, 4 and 2 min, respectively.

In the single-use group, mean perioperative processing time was 33 min (Table 4). Set preparation was the longest step, taking 17 min and accounting for 52% of the total time. The time of ordering, order reception and transport to OT was 10, 5 and 1 min, respectively.

In total, a mean gain of 143 min ($p < 0.001$) of processing time was obtained with the single-use device, mainly due to the absence of pre-disinfection, sterilization and NSI assembling.

**Fig. 2** Sets required for posterior lumbar fusion with pedicle screws, rods and interbody cage: reusable device CD Horizon® Legacy™ (Medtronic) Spinal System and Capstone® cage (Medtronic) (top image); on the bottom, single-use SteriSpine™ PS and LC (Safe Orthopaedics®) (bottom image)

The reusable device was not available at procedure start in two cases. In one case, it was delivered during the course of the surgery. In the other case, surgeon had to use another set because of reusable device unavailability.

Weight of instruments was 42 kg (for three containers) for reusable device versus 1.2 kg for single-use device (Fig. 2).

From an economic perspective, processing of reusable device costed 58.30€ per procedure in terms of staff and

consumables. With a cost of 23.90€ and 16.32€, respectively, assembling and sterilizing the instruments accounted for 69% of the total cost (Table 3).

For single-use device, main resource consumption came from instrument preparation (7.30€) and ordering (3.20€). Device reception and transport to operating theatre were estimated, respectively, at 1.79€ and 0.53€. With a per-weight cost of 120€/ton for general waste and 610€/ton for infectious–risk, single-use device waste management was 1.37€ per device (Table 4). There was no sterilization cost for single-use device.

Instrument sterilization cost per metre cube ($m^3$) is estimated to be 900€ (French National Standard: "Anger Basis" 2014). A mean of three boxes was used per surgery in the reusable group, each representing a volume of 0.05 $m^3$. Therefore, sterilization cost for these instruments was 137.25€. Adding the cost of perioperative staff, total cost for reusable device was 195.55€ representing an additional 181.36€ per surgery compared to single-use device (Table 4).

## Discussion

Cost analysis is important for healthcare facilities searching for saving measures. Single-use device may reduce the processing cost owing to the absence of sterilization after usage. This study compared the economic and organizational impact on a hospital of single-use and reusable devices in one- or two-level lumbar spinal fusion (Table 5).

Single-use device led to a cost reduction of 181€ per procedure. The higher cost of reusable device was due to assembling and sterilizing steps which amounted to 69% of the total expense. Considering that in France, four screws and two rods cost 700€ to the hospital, price subsequently reimbursed by the National Health Service, this gain represents 26% of the device purchase cost. One must know that implant purchase costs of reusable and single-use devices were identical since it is a fixed cost negotiated between companies and our National Health System. Moreover, companies of this study only charged for the implants but not for the instruments. This may vary amongst countries and impact on device's cost-effectiveness. In a study evaluating disposable and reusable biopsy forceps, Deprez et al. [13] found that total purchase and reprocessing costs for reusable biopsy forceps were 25% of those of disposable devices due to the high purchase price of single-use instrument. In a study comparing single-use and conventional sets for distal volar plating [14], conventional set was cheaper since additional screws not available in the single-use set were required in 77% of cases despite a lower purchase price of single-use set. Since instruments and implants are packed in separated kits, pedicle screws and rods sizes were not an issue with the single-use device.

Some elements of sterilization cost were not evaluated in our study underestimating cost of reusable device. It includes machine amortization, repair, water, energy, detergents, personnel training, etc. [4]. Instead, we used a national referential (Anger Basis) which indicated the cost of sterilization per $m^3$ of box. Three boxes (0.17 $m^3$) per procedure were used on average. In a study comparing single-use and reusable laparoscopic instruments, Schaer et al.'s study, the so-called hidden costs of reusable instruments including depreciation, repair, maintenance, replacement, cleaning and sterilization, amounted to 56% of the total expense.

Similarly, Schaer et al. [9] reported a sevenfold higher estimated annual expense with single-use laparoscopic instruments compared to reusable instruments despite high "hidden costs" of the reusable device. In Schaer et al.'s study, the so-called hidden costs of reusable instruments included depreciation, repair, maintenance, replacement, cleaning and sterilization and amounted to 56% of the total expense. In our study, we were unable to measure some parameters involved in the sterilization cost and which may have further increased the cost of reusable device. It includes machine amortization, repair, water, energy, detergents, personnel training, etc. [4]. Instead, we used a national referential (Anger Basis) which indicated the cost of sterilization per $m^3$ of box and included this cost with a mean of three boxes (0.17 $m^3$) per procedure.

Single-use device was associated with a significant reduction of 143 min in the perioperative steps in comparison with reusable device mainly due to the absence of the pre-disinfection, instrument assembling and sterilization steps. From an organizational perspective, it may lead to improved allocation of OT and SPD's staff members. In addition, this may decrease the risk of unexpected event in the perioperative process which could have detrimental consequences on both patient's clinical state and OT's organization. Bhadra et al. [15] suggested that the use of single-use instruments, cutting blocks and trials in total knee arthroplasty would improve OR efficiency. By improving efficacy, single-use devices allow hospitals to conform to the definition of quality of care as reported by the World Health Organization [16]. This is particularly valuable in major trauma hospitals, in which both elective and emergent surgeries are performed.

**Table 5** Outcomes of cost per intervention analyses

| | Reusable | Single-use | Cost difference between groups |
|---|---|---|---|
| Micro-costing | 58.30 € | 14.19 €* | 44.11 € ($p < 0.05$) |
| Micro-costing + sterilization costs | 195.55 € | 14.19 €* | 181.36 € ($p < 0.05$) |

*Infectious clinical waste costs, € euros

Posterior lumbar fixation is not infrequent in trauma. In case of numerous spinal operations, SPD may not be able to resupply OT in due time which can cause delay or cancellation. In this study, the reusable device was not reprocessed in time in two cases. Single-use device seems to be a sustainable solution to ensure spinal sets' availability. Nevertheless, operation with single-use implants always requires reusable instruments such as retractors and forceps, so do the reusable implants. Since these basic instruments were identical for single-use and reusable implants, they were not taken into account in the cost comparison. Similarly, each operation required consumables such as gauzes, suction and drapes which were considered in equal quantity in both groups hence not factored in.

Single-use device has some non-monetary advantages. On average, three heavy boxes were used with reusable device. Single-use devices are delivered in lighter boxes that facilitate handling (Fig. 2). This contributes to musculoskeletal disorders prevention of hospital caregivers. Secondly, single-use device may improve safety by limiting the risk of contamination by infectious agents partly because it requires less handling by OT's staff. Mont et al. [11] showed a significant reduction in compromised sterility episodes in total knee arthroplasty when using single-use instrumentation, cutting blocks and trials. Litrico et al. [17] reported an infection rate at 2% in a series of 49 patients who underwent one-to-three-level lumbar fusion with single-use device and 6% in an older series of 100 patients treated with reusable device. They concluded that preservation of screws and rods in sterile packs until ready for insertion reduces their exposure to air-borne bacteria in the OR and eliminates their contamination through repetitive hospital sterilization.

Single-use device implies waste disposal issues. Currently, it is discarded in the sharps' container. It produces infectious–risk waste that cannot be recycled or reprocessed. Manufacturer attempted to minimize the quantity of instruments. The boxes of single-use device contain 19 instruments due to its modularity (Fig. 1), whereas reusable device sets contain 25–35 instruments. For the reusable device, the number of disinfecting wash cycles (requiring water, energy and detergents which are toxic to environment) contributes to the energy cost of manufacturing and environmental pollution as do the processes of post-use destruction (waste management) for single-use devices.

Despite various publications on micro-costing [18–20], there is currently no standardized method of micro-costing analysis. Costs may be measured with different methods, including direct observation of expenditures and use of administrative resources, by expert panels or by individual questionnaires [21]. In this study, we chose to estimate costs using a series of direct observations. This methodology has several advantages, the main ones being precision and reliability of the data recorded [5]. In addition, measuring directly within the clinical setting allows an objective identification of the resource consumption and better understanding of the perioperative processing. With a specific circuit for each, a micro-costing analysis allows any variability to be factored in. As such, mean cost of processing was 58.30€ for reusable device, ranging from 38.32€ to 101.50€. This variability was related to the diversity amongst interveners during sterilizing, some of whom had extensive experience and much faster task execution as a result. Also, high turnover in OT's staff and instruments means there is a learning curve for inexperienced scrub nurses and surgeons to master the use of single-use instruments as seen by the longer operation duration, however not significant.

Using micro-costing methodology is associated with various limitations such as operator-dependent evaluation of time and cost measurement for each step. In addition, this method cannot be used systematically (e.g. in case of unexpected procedure). Performing a micro-costing study is difficult when processing requires several simultaneous steps. We acknowledge that not every cost was included in the analysis. The fixed costs such as amortization of reusable instruments and sterilization materials, maintenance of materials and premises (microbiological testing, maintenance, repairs, etc.) as well as consumables (water, electricity) were difficult to measure. We had to estimate this cost based on a national referential (anger basis) that indicated the cost of sterilization according to the volume of boxes. Also, we did not evaluate ease-of-use and surgeon's satisfaction. Some concerns about the risk of instrument breakage were brought to the manufacturer. Single-use device was used only in short lumbar fusion but might not be as performant as reusable device for long fusion with deformity correction.

## Conclusion

Single-use medical device allowed a substantial time gain on perioperative processing and overall procedure cost reduction in short lumbar spinal fusion surgery. They may also improve the quality of care by limiting the number of delayed operations and contribute greatly to improve hospital efficacy. However, it implies additional expenditures such as costs associated with more frequent ordering and extra waste management. We have decided to have both single-use and disposable devices in our operating theatre in order to avoid delays in surgery.

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## Compliance with ethical standards

**Conflict of interest** C Bouthors, J. Nguyen, L. Durand, A. Dubory and S. Raspaud declare that they have no conflict of interest.

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