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Original article

What is the cost burden of surgical implant waste? An analysis of surgical implant waste in an orthopedics and trauma surgery department of a French university hospital in 2016

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ABSTRACT

Background: During an orthopedic or trauma surgery procedure, when an implantable medical device is unpackaged, not implanted and cannot be resterilized, it is considered "waste". The cost burden falls on the hospital. The French Social Security Code provides for add-on reimbursement for certain expensive or very specialized devices (supplementary list of costly implants). To allow its restocking without linking it to a patient or reimbursement request, the wasted implant is tracked in a computerized database. The economic impact of these wasted implants is not known in France. This led us to conduct a retrospective study: 1) to determine the percentage and number of wasted implants, 2) to identify elements related to the surgery that impact implant waste.
Hypothesis: Various elements of the surgical environment (type of procedure, specialty, surgeon experience, time of year) can independently contribute to the non-implantation of a medical device.
Methods: We carried out a retrospective observational study of data collected prospectively in the database of our teaching hospital in 2016. The primary outcome was the percentage of wasted implants. The secondary outcome was the mean cost of these wasted implants. These parameters were determined for all the implants used in orthopedics and trauma surgery and tracked in this department, then for each variable hypothesized to led to non-implantation. Our analysis was descriptive, then comparative.
Results: In our database, 29,073 devices were tracked (€3,761,180), of which 1995 devices were wasted (6.9%). The total cost of the wasted implants was €179,193 (4.8% of the overall cost). The breakdown of the wasted implants was 430 (4.4%) from the add-on list (average cost of €293.10) versus 1565 implants associated with the hospital's diagnosis-related group payment system (average cost of €33.90). Trauma surgery procedures had significantly more wasted implants than orthopedic surgery (1135 vs. 860 ($p < 0.01$)), although the individual cost was less (€59.20 vs. €130.10 ($p < 0.01$)). Fracture fixation implants were more likely to be wasted than ligament reconstruction or arthroplasty implants, with a lower mean cost. More implants were wasted during hip arthroplasty than during other arthroplasty procedures. Less experienced surgeons wasted more implants than more experienced surgeons (1087 vs. 905 ($p < 0.01$)) but these implants cost less (€69.20 vs. €114.80 ($p < 0.05$)). The percentage of implants wasted was higher during the resident changeover period relative to the other months of the year (772 vs. 1223 ($p < 0.01$)).
Discussion: This study is the first attempt at quantifying the number and cost of wasted implants in the context of orthopedics and trauma surgery at a teaching hospital in France. While trauma surgery is associated with more wasted implants, the cost burden is higher in orthopedics. Surgeons, by virtue of their experience and teaching mandate, have a decisive role managing this cost burden.
Type of study: IV, Retrospective study.

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1. Introduction

Implanting a medical device (MD) is associated with traceability requirements for sterility [1,2], financial [3,4] and good practice [5] reasons. In France, most of the MDs used during a patient's hospitalization are included in the cost of the stay (Diagnosis-Related Group (DRG)-based payment system). This is the case for most fracture fixation implants. The French Social Security Code provides for add-on reimbursement for certain expensive or very specialized devices (supplementary list of costly implants). These devices must be registered on the French list of reimbursable products and services (LPPR) and the list of devices billable over and above inpatient services. During a surgical procedure, the MD is tracked in a computerized database to ensure the traceability of its outcome ("implanted" or "wasted"), while an interface with the billing software provides financial traceability. For trauma indications, there is no regulatory requirement to track fracture fixation implants [1,2]. In fact in trauma surgery, many devices can be resterilized, making it impossible to track them by lot number. Nevertheless, if they are damaged during the procedure and disposed of, they must be tracked for stock management purposes.

Several teams, especially in the United States, have looked into issues surrounding surgical implant waste. They found significant reductions in the quantity and cost after an awareness program was implemented for operating room staff [6–10]. Epstein et al. [10] showed that training for neurosurgeons helped to reduce the surgery costs during cervical discectomy from 20% to 5.8%. Zymiel et al. [11] suggested that orthopedic surgeons are directly responsible for wasted implants during the hip and knee arthroplasty procedures they analyzed in 2010, and that it was essential to include them in the planning process.

Recent health economics studies in orthopedics and trauma surgery showed that French surgical teams are aware of the financial impact of the surgical techniques and materials they use [12]. At the time of that study, to our knowledge, there was no published data in France on the management of wasted implants. At our hospital, an analysis of these wasted implants had never been carried out. In this context, wasted implants are a net financial loss for the healthcare facility.

This led us to conduct a retrospective study for the year 2016:

- to determine the percentage and number of wasted implants;
- to identify elements related to the surgery that impact implant waste.

We hypothesized that various elements of the surgical environment (type of procedure, specialty, surgeon experience, time of year) can independently contribute to the non-implantation of a medical device.

2. Material and methods

2.1. Analyzed medical devices

This was a retrospective observational study of data collected prospectively. Since the analysis of anonymous data from our university hospital's information technology (IT) system was purely retrospective, approval from our institutional review board was not necessary. All of the available traceability data in the operating room software was extracted during the period 01/01/2016 to 31/12/2016. The database included 76,658 devices initially. Selection of the "implanted" and "wasted" orthopedic and trauma devices was done as described in Fig. 1.

Fracture fixation implants, whether sterile and single-use or supplied non-sterile but resterilizable, were included in the analysis. Lost implants were differentiated from wasted implants. The lost implants were either:

- implanted, re-ordered, but not tracked;
- implanted, not tracked, not re-ordered;
- expired and not renewed.

Lost implants were not considered in the study since they were not tracked but are a source of bias in our analysis.

2.2. Assessment methods

The primary outcome was the percentage of wasted implants, which is the ratio between the number of wasted implants and the number of implants tracked. The secondary outcome was the mean cost of the wasted implants, which is the ratio between the cost (ex-tax) of the wasted implants and the number of wasted implants. Some wasted devices are not billed (cost of €0) as they are a component of a fracture fixation system or joint replacement system; they are provided as an accessory by the manufacturer with a reference number for tracking. For example, a fixation screw or cap, or cement restrictor or parts of a modular implant; in all, there were 153 non-billable wasted implants (cost of €0) in our orthopedic and trauma department in 2016. All of the parameters were determined for all the orthopedics and trauma devices tracked in the operating room specific to this department, then based on the type of reimbursement for the device. Next, a subgroup analysis was carried out on the implant's specialty, type of procedure, surgeon tenure, and time of year.

2.3. Statistical analysis

A descriptive analysis of the percentage and cost of wasted implants and then a comparative bivariate analysis of several contributing factors was carried out. The Chi^2 test was used to compare the quantities of wasted implants. Student's t test was used to compare the mean implant costs when the data were distributed normally. If not, a Wilcoxon test was used to compare two groups and a Kruskal–Wallis test to compare more than two groups (non-parametric methods). Since multiple comparisons were performed in some cases, the Hochberg method was applied to counter the increase in the type I risk (alpha) when drawing conclusions based on the various comparisons [13]. A p value of 5% or less was considered statistically significant. Statistical tests were carried out with SAS software (version 9.3, SAS Institute, Cary, NC US) [14].

3. Results

In 2016, 29,073 implantable MDs for orthopedics or trauma surgery were tracked; these implants cost a total of €3,761,180 (ex-tax). Among these, 1995 implants were wasted, which represents 6.9% (1995/29,073) of the tracked implants. The cost of these wasted implants was €179,193, which is 4.8% (179,193/3,761,180) of the total cost of the tracked implants (Table 1).

The percentage of wasted implants from the add-on list (430/9778 (4.4%)) was significantly less than that of wasted implants linked to the hospital's DRG payment system (1565/19,295 (8.1%)) ($p < 0.05$). Conversely, the mean cost of a wasted implant from the add-on list (€293.1 ± 265.2 [0 to 1344.2]) was significantly higher than the mean cost of a wasted implant linked to the hospital's DRG payment system (€34.0 ± 69.2 [0 to 791.1]) ($p < 0.01$).

There were more wasted implants during trauma surgery than orthopedic surgery procedures (1135 vs. 860, $p < 0.01$) (Table 2). However, the mean cost of a wasted orthopedic implant

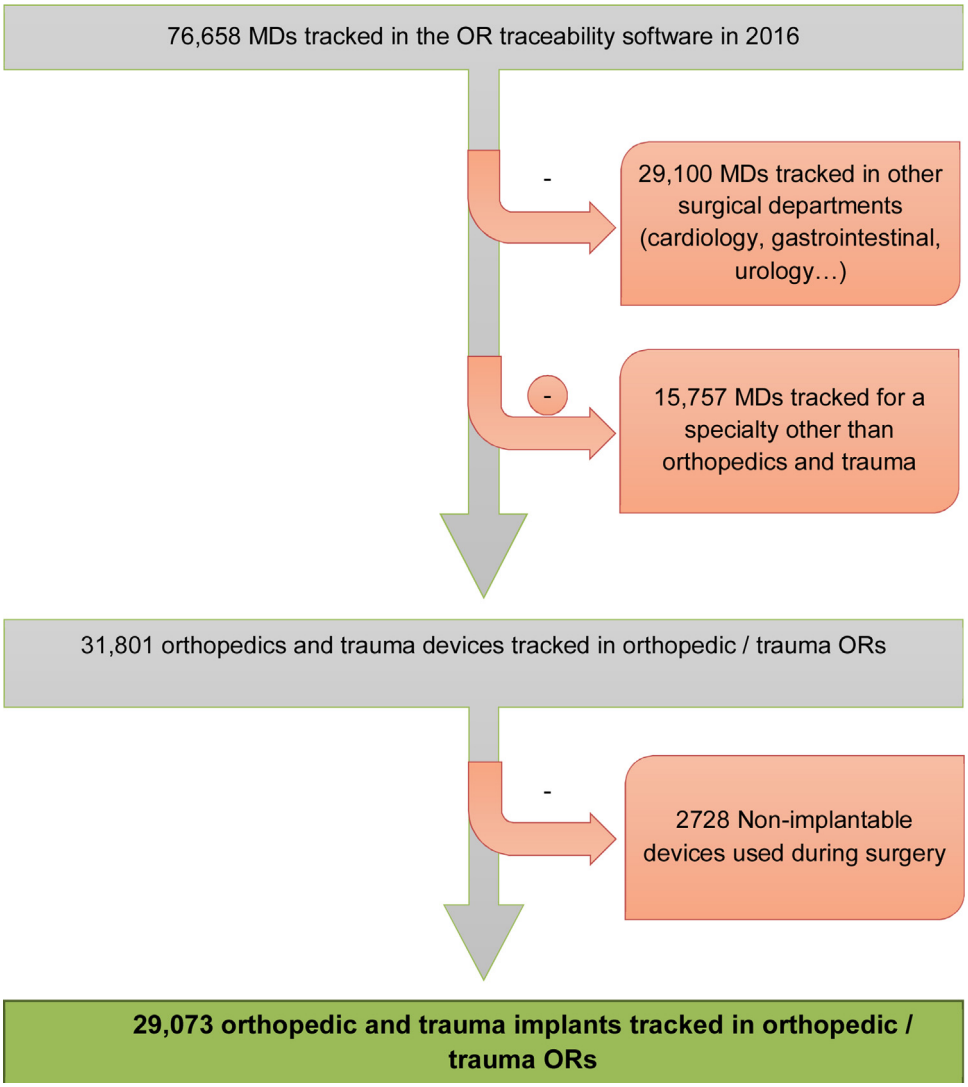

Fig. 1. Flow chart summarizing the collection of implantable medical device data.

Table 1
Number and cost of wasted implants in orthopedic and trauma surgery at our hospital in 2016.

Traceability of implantable MD	Wasted		Implanted		Total	
	Number of implants	Cost in €	Number of implants	Cost in €	Number of implants	Cost in €
Hospital DRG	1565	53,156.5	17 730	844,376.6	19,295	897,533.1
Add-on list	430	126,036.5	9 348	2,737,610.8	9778	2,863,647.4
TOTAL	1995 (6.9%)	179,193.1 (4.8%)	27 078	3,581,987.4	29,073	3,761,180.5

MD: Medical device, DRG: Diagnosis-related group.

(€130.1 ± 209.0 [0 to 1344.2]) was significantly higher than that of a trauma implant (€59.2 ± 134.0 [0 to 875.7] ($p < 0.01$)).

The number of wasted implants was related to the specialty (Table 2). More fracture fixation implants were wasted than arthroplasty implants, with a lower mean cost. There were significantly more implants wasted during a hip arthroplasty procedure than during other arthroplasty procedures. There were 128 implants wasted in the context of ligament reconstruction (128/1813 (7.1%)). The cost of a wasted hip arthroplasty implant (€391.0 ± 292.0 [0 to 1117.4]), knee implant (€362.7 ± 312.8 [0 to 1344.2]), shoulder implant (€455.0 ± 407.9 [0 to 1238.8]) or ligament reconstruction device (€188.8 ± 46.0 [0 to 453.0]) was significantly greater than the mean cost of a fracture fixation implant (€33.9 ± 66.9 [0 to 626.8]). During hip arthroplasty, cups (69/1081 or 6.4%) and inserts (41/623 or 6.6%) were wasted most often. During knee and shoulder arthroplasty, the inserts were wasted most often (18/335 or 5.4% and 5/75 or 6.7%). Screws were the most commonly wasted implants in the context of trauma surgery (1334/14,642 (9.1%)).

There was a significant relationship between the number of wasted implants and the surgeon's experience. The least experienced surgeons wasted more implants (1087 vs. 905 ($p < 0.01$)) but the average cost of these implants was less (€69.2 ± 134.0 [0 to 1117.4] vs. €114.8 ± 209.8 [0 to 1344.2]) (Table 2). There was no correlation between the number of wasted implants (p: − 0.3106, $p = 0.12$) or cost of wasted implants (p: − 0.2335, $p = 0.25$) and the number of surgical procedures performed by a single

Table 2
Number and mean cost of wasted implants by factor.

Factor		Number of wasted implants	*p*-value	Mean cost of wasted implant (€)	Range of costs of wasted implants [min[a]; max]	*p*-value
Procedure type	Fracture fixation	1543 (8.3%)	<0.01	33.9	[0; 626.8]	< 0.0001
	Ligament reconstruction	128 (7.1%)		188.8	[0; 453.0]	
	Hip arthroplasty	195 (4.9%)		391.0	[0; 1117.4]	
	Shoulder arthroplasty	18 (4.3%)		455.0	[0; 1238.8]	
	Knee arthroplasty	41 (2.4%)		362.7	[0; 1344.2]	
Specialty	Trauma	1135 (7.4%)	<0.01	59.2	[0; 875.7]	<0.01
	Orthopedics	860 (6.3%)		130.1	[0; 1344.2]	
Surgeon experience	Fellowship	1087 (8.2%)	<0.01	69.2	[0; 1117.4]	<0.05
	Senior	905 (5.8%)		114.8	[0; 1344.2]	
Time of year	May-June and November-December	772 (7.8%)	<0.01	NA	NA	NA
	Other months	1223 (6.4%)		NA	NA	NA

NA: not applicable.
[a] The minimum values of "0" correspond to items not billed by the suppliers (fixation screw or cap, cement restrictor or modular implant component), thus 153 non-billed implants (cost of 0 €) in the entire orthopedic and trauma surgery practice in 2016.

surgeon. During the resident change-over period (May to June and November to December), there was a significant increase in the number of wasted implants relative to the other months of the year (772 vs. 1223 ($p < 0.01$)) (Table 2).

4. Discussion

This is the first study to quantify the number and cost of wasted surgical implants at a French teaching hospital [15]. In 2016, the 1995 orthopedic or trauma surgery implants that were wasted cost the hospital €179,193 (ex-tax). We also found that the number of add-on list implants wasted was less than the number of DRG-related implants wasted. Nevertheless, the former cost significantly more. Given the reimbursement scheme for these implants, they are not covered by the insurance scheme in the context of the patient's hospital stay. Thus they are a net loss for the hospital.

More implants were wasted in the OR during trauma surgery; however these implants cost less on average. Performing fracture fixation seems to generate implant waste. The emergency context in which these trauma implants are used may explain the high number of wasted implants. Bosco et al. [16] had similar findings: 30% wasted trauma implants, with nearly $214,000 in wasted implant cost in arthroplasty. Since most arthroplasty implants have a higher unit cost than fracture fixation implants, the cost of wasted implants is logically higher in the orthopedic surgery context.

As shown by other teams [6,11,17], hip arthroplasty procedures have more wasted implants than other arthroplasty procedures. In the context of hip arthroplasty, the cup was the implant type wasted the most. Its fixation is a technically demanding step. A lack of immediate stability may lead the surgeon to rework the acetabulum or to choose different fixation method (with cement). For both knee and shoulder arthroplasty, the insert was the implant type wasted the most, as it is the most subjective aspect of the construct. During ligament reconstruction, the tibial screw was most often wasted. The poor stability felt when a screw is placed in less dense bone may lead the surgeon to selecting a large size instead.

A surgeon's experience (number of years performing surgery) contributes to reducing the number of wasted implants (more than the number of procedures) [6,16]. The cost of wasted implants is higher for senior surgeons. We think this observation can be explained by the use of more costly implants in the context of innovative procedures or the treatment of more complex clinical cases. Our hypothesis is supported by the fact that the number of wasted implants jumps during the resident change-over periods. [7,11]. Other factors such as the scrub nurse's experience or the presence of an implant manufacturer's representative in the OR can have a direct impact on the number of implants wasted [15].

Our study was a preliminary study aiming to describe the overall context of "non-implantation" and to propose corrective and preventative actions. These actions include raising the teams' awareness about this problem, improving the traceability protocol (particularly IT systems) and advocating for well thought-out use of implantable MDs that follow good practices and the manufacturers' recommendations. Some of these actions have been successfully implemented; for example, the percentage of wasted implants went from 44% to 24% after implementing an educational program for spine surgery [7]. We are planning to evaluate the long-term efficacy and implementation of such corrective measures at our hospital.

Our study has several limitations:

- the first is the exhaustivity of the traceability data leading to underestimation. Fracture fixation implants are excluded from the medical device vigilance decree in France related to legal requirement for sterility traceability [1,2]. Without these legal requirements, and with implants available in bulk and resterilizable, users may not have tracked them or tracked them using the wrong reference numbers;
- the second bias is the risk of overestimating the results. Given the parameterization of MDs in the financial and economic management software, users can also track non-implantable MDs in the OR traceability software. Certain devices such as K-wires are a problem because— depending on the type of procedure and/or surgeon preferences—they can be either implantable (fracture reduction) or non-implantable devices (guide wire for screw positioning);
- the third bias is related to identifying the surgeon. In our OR software, we do not have the option to record whether the procedure was done by a senior surgeon or by a resident supervised by this senor surgeon. Such information would have allowed us to refine the analysis;
- lastly, we did not analyze the reasons for non-implantation, such as loss of sterility, unpackaging errors, failed implantation due to anatomy/patient, incorrect surgical use and medical device vigilance. While this information was not collected, it would be relevant for better understanding the reasons for non-implantation.

5. Conclusion

This study was the first one to quantify the number of implants wasted during orthopedic and trauma surgery at a university hospital in France. While more implants are wasted during trauma surgery than orthopedic surgery, the mean cost is higher for the

orthopedic implants. Our analysis points to technical difficulties during an emergency procedure or the complexity of implant selection during arthroplasty surgery as driving implant waste. Surgeons, by virtue of their experience and teaching mandate, have a decisive role in advocating for good usage of these implants and managing the cost burden.

Disclosure of interest

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Authors' contributions

T. Laurut: Primary author Study design, data collection, analysis and interpretation of findings.

C. Duran: Critical review.

A. Pages: Statistics.

MC Morin: Study coordinator, critical review and approval of submitted manuscript.

E. Cavaignac: Assistance with methods, critical review and final approval of submitted manuscript.

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