Software-related recalls in computer-assisted hip and knee arthroplasty

Title: Software-related recalls in computer-assisted hip and knee arthroplasty

Authors:

Francesco Castagnini°, Marco Maestri°, Enrico Tassinari°, Claudio Masetti°, Cesare Faldini*^, Francesco Traina°^

°MD, Ortopedia-Traumatologia e Chirurgia protesica e dei reimpianti d'anca e di ginocchio, IRCCS Istituto Ortopedico Rizzoli, Via Pupilli 1, Bologna 40136, Italy

*Clinica Ortopedica e Traumatologica I, IRCCS Istituto Ortopedico Rizzoli, Via Pupilli 1, 40136, Bologna, Italy.

^Orthopaedics and Traumatology, University of Bologna DIBINEM, 40123, Bologna, Italy

Study conducted in Bologna, Istituto Ortopedico Rizzoli

Corresponding author:

Francesco Castagnini, MD

Ortopedia-Traumatologia e Chirurgia protesica e dei reimpianti d'anca e di ginocchio, IRCCS Istituto Ortopedico Rizzoli,

Via Pupilli 1, Bologna 40136, Italy

E-mail: francescocastagnini@hotmail.it

ORCID ID: 0000-0002-3567-9194

Tel: +39 0516366148

Fax: +39 051-6366416

Short title: Investigating Medical Device Recalls

DECLARATIONS

CONSENT TO PARTECIPATE

Not applicable

CONSENT TO PUBLISH

Not applicable

AVAILABILITY OF DATA AND MATERIALS

Data are available as supplementary materials

CODE AVAILABILITY

Not applicable

FUNDING

The authors declare that no funds, grants, or other support were received during the preparation of this manuscript.

CONFLICT OF INTEREST

The authors have no relevant financial or non-financial interests to disclose.

AUTHORS' CONTRIBUTION

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Francesco Castagnini, Marco Maestri, Enrico Tassinari. The first draft of the manuscript was written by Francesco Castagnini and Claudio Masetti. Cesare Faldini and Francesco Traina critically revised the first draft. All authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

ETHICS APPROVAL

The ethics approval was waived due to data anonymization and public database query.

SOFTWARE-RELATED RECALLS IN COMPUTER-ASSISTED HIP AND KNEE ARTHROPLASTY

ABSTRACT

Purpose

Computer-assisted arthroplasty supports the surgeons in planning, simulating and performing the replacement procedure, using robotic or navigation technologies. However, the safety of the technology has not been widely ascertained. Food and Drug Administration (FDA) database was interrogated about software-related recalls in computer-assisted arthroplasty, aiming to assess: 1) the incidence; 2) the root causes; 3) the actions taken due to recalls.

Methods

The Medical Device Recalls database was investigated about software-related recalls in computer-assisted hip and knee arthroplasty surgery, between 2017 and 2022. The incidence of the software-related recalls, the root causes according to FDA and manufacturers, and the corrective actions taken by firms were determined.

Results

18 recall numbers could be identified (1.6%), corresponding to 11 recall events. 4634 units were involved. The FDA determined root causes were: software design (66.6%), design change (22.2%), manufacturing deployment (1, 5.6%), design manufacturing process (5.6%). Among the manufacturers' reasons for recalls, a specific error was declared in 16 cases (88.9%). In 7 cases (43.8%), a coding error about lower limb alignment assessment was identified. 17 software-related recalls (94.4%) were classified as class 2, only one case class 3 (5.6%). Return of the device was the main action taken by firms (8, 44.4%), followed by software update (7, 38.9%).

Conclusion

Software-related recalls in computer-assisted hip and knee arthroplasty were quite uncommon among all the recalls, deemed non-life threatening and usually due to software design errors. The main actions taken by manufacturers were the return of the device or the software update.

KEYWORDS: medical device recalls database; malfunction; health information technology; robotic; navigation; software design

DATA AVAILABILITY: data are available as supplementary material

LEVEL OF EVIDENCE: IV

MAIN TEXT

INTRODUCTION

Computer-assisted arthroplasty was developed to help the surgeons improve the precision, the tissue handling, the velocity and the reproducibility of the procedure [1,2]. These theoretical advantages led to a more widespread adoption of computer-assisted arthroplasty among hip and knee arthroplasty procedures: in 2015, computer-assisted technologies were involved in 11.6% of all the total knee arthroplasties and 5.2% of all the total hip arthroplasties, according to the New York Statewide Planning and Research Cooperative System [3].

Literature confirmed that computer-assisted hip and knee arthroplasty improved component positioning and alignment, but these benefits were counterbalanced by increased costs, increased operative times, and possible malfunctions [4,5]. Malfunctions are well-known downsides of computer-assisted surgery: with an upward trend over the time, malfunctions caused damages to patients in 0.5%-5.4% of the cases and mortality in 0.0013%-0.0061% of the cases in surgery (without discrimination of surgical specialties) [6]. However, these data concerning different surgical specialties may be underestimated, as malfunctions reporting in computer-assisted surgery was biased by delays, underreporting and inaccuracies in case files, even in case of fatality [7].

Among malfunctions in computer assisted surgery, software-related ones are gaining attention, due to the incremental adoption of software in medical device systems: between 2005 and 2011, 19.5% of all the recalls could be related to software malfunctions [8]. Nevertheless, software-related malfunctions are still poorly investigated in orthopaedics: specifically, there is no study assessing the incidence and the reasons for software-related recalls in computer-assisted hip and knee arthroplasty. The medical device recalls database run by Food and Drug Administration (FDA) was interrogated about software-related recalls in computer-assisted hip and knee arthroplasty in the last 5 years (2017-2022). We sought to assess: 1) the incidence; 2) the root cause; 3) the actions taken due to recalls.

METHODS

The Medical Device Recalls database is a Food and Drug Administration (FDA) database collecting data about defective medical devices on the US market subjected to recall procedures since November 2002 [9]. Devices are considered defective when adverse effects and potential health risks are identified and attributed to the use of the device (when a device is misbranded or adulterated) [9]. A recall occurs when the manufacturer takes a removal or correction actions (excluding market withdrawal, stock recovery, safety alert) of a marketed defective product that FDA considers violating the Federal Food, Drug and Cosmetic Act or might require a legal action. The malfunction is usually identified by the manufacturers and notified to FDA within 10 working days. Even FDA itself may identify defective devices after inspection or warnings, when products may cause harms and pose risks to the public health: in this case, FDA may issue a “medical device notification order”. The manufacturer provides data about the malfunctioning device, the description of the event, the harms or the injuries that have occurred, the root cause, the actions taken and the recall strategy.

The manufacturer had the responsibility of improving the product quality for the future. The FDA classifies the recall according to the health risks. Class I recall describes "a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death" [9]. Class II recall is "a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote" [9]. Class III recall is "a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences" [9].

The FDA database was enquired about software-related recalls, on 26 July 2022 [10]. The root causes "software design change", "software manufacturing/software deployment", "software change control", "software design", "software design (manufacturing process)", "software in the use environment" were investigated. The recall date was between 1st January 2017 and 1st January 2022. The results were manually screened, consulting the FDA report and, when necessary, the manufacturer website. Only recalls strictly dealing with hip and knee arthroplasty were included: in particular, the software should be involved in pre-operative planning and/or surgical procedure.

The recalls dealing with a software involved in general surgical procedures, surgical operating table control, fluoroscopic assessment, radiological assessment not including pre-operative arthroplasty planning, labeling, packaging, storage sterilization, were excluded. The root causes "under investigation by firm" and "unknown/undetermined by firm" were excluded.

The incidence of the software-related recalls in computer-assisted arthroplasty was determined. The total amount of involved devices were specified. The root causes according to manufacturers and FDA were listed, the FDA classification was provided, as well as the premarket notification process. The removal or correction actions taken by manufacturers were specified.

A descriptive statistical analysis was conducted.

The institutional board review was waived due to data anonymization.

RESULTS

1122 software-related recalls were identified between 1st January 2017 and 1st January 2022. Out of them, 915 recalls (80.8%) were due to software design [FIGURE 1]. The distribution over the time was detailed in the table [TABLE 1].

Incidence

Between 2017 and 2021, 18 different recall numbers involving total hip and knee arthroplasty could be identified, 1.6% (18/1122) of the whole. The 18 recall numbers corresponded to 11 recall events: 7 recall numbers were due to Trumatch CT (Depuy Orthopaedics, Warsaw, US) event (88522) and 2 recall numbers were due to RIO (Mako Surgical Corporation, Stryker, Kalamazoo, US) event (77950).

All the recalls involved 4634 units: a mean value of 272.6 units was involved in every recall number (range: 1-3232, one recall was not available). 17 software-related recalls out of 18 (94.4%) involved products distributed worldwide.

Root cause

The FDA determined root cause were: software design (12, 66.6%), design change (4, 22.2%), manufacturing deployment (1, 5.6%), design manufacturing process (1, 5.6%).

Among the manufacturer root cause, all but two cases (16/18, 88.9%) declared a specific error. In 7 cases (7/16, 43.8%), a coding error jeopardizing the lower limb alignment assessment was identified. In 2 cases (2/16, 12.5%), software discrepancies not showing all the constants were traced. All the other causes occurred once (1/16, 6.3%): inadequate image resizing and inaccurate measurements, miscalculation of femoral resection depth, digital templates with incorrect files, software crash, problems with destination server, wrong data loading, incorrect unit of measure for femoral cut measurements.

17 software-related recalls out of 18 (94.4%) were classified as class 2: only one case (5.6%) was class 3. 7 recalled devices (38.9%) were cleared through the PMA premarket approval, 11 ones (61.1%) through the 510(k) premarket notification process.

Actions taken due to recalls

Return of the device was the main action taken by firms (8 cases, 44.4%), followed by software update (7, 38.9%). In two cases (11.1%), the only action taken was communication to the product specialist and branch managers (the problem was considered “not a customer facing issue”). In one case (5.6%), a strategy of communication and advice about use modifications was adopted. At the time of the analysis, 10 recalls out 18 (55.5%) were terminated. The mean time from notification to termination was 204 days (range: 1-696 days).

DISCUSSION

According to the Medical Device Recalls database, software-related recalls in computer assisted hip and knee arthroplasty were 1.6% of the whole software-related recalls in the last five years. Defective devices were more than 4000 units and were distributed worldwide. The principal root cause was software design errors (66.6%) and usually resulted in inaccurate lower limb alignment evaluation. Return of the device and software update were the two most common actions taken by manufacturers.

According to the FDA database, the orthopaedic specialty is the main contributor to medical device recalls (15%) nowadays, with software related recalls accounting for only a small part of them (around 2% of all the orthopaedic recalls in 2015-2019) [11,12]. This study demonstrated that software related recalls in computer-assisted arthroplasty rarely occur in the last 5 years (1.6% of all the software recall numbers in 2017-2021, with 11 recall events identified). However, more than 4000 units were ultimately involved, worldwide. Software-related malfunction is an emerging issue: the progressive diffusion of computer-assisted surgery (more

than 30% of the arthroplasty procedures in Australia are navigation-based) makes software reliability and safety crucial for all the healthcare stakeholders [1].

The root cause leading to recalls was software design error in two thirds of the cases: this is not surprising, as more than 80% of all the devices were recalled due to software design defects [TAB 1]. It should be stated clearly that, to our knowledge, there is no publicly available, FDA-released document specifying the definition of the six software-related root causes (which are mutually exclusive). This is a very notable limit of the FDA database, which is even sharper when public data provided by manufacturers turn out brief and incomplete. Thus, accurate classifications and adequate speculations on the aspects to improve are substantially impeded. However, in almost all the cases manufacturers identified a quite specific error: most of these cases were correlated to inadequate measurements and calculations. Considering that computer-assisted arthroplasty should improve the precision of the surgeon eye, these malfunctions are quite upsetting and weaken the rationale of computer-assisted arthroplasty. Luckily, none of the recalls was considered life-threatening by FDA. Among the software-related recalls, more than one third of the recalled devices were cleared through the PMA premarket approval, which is the most stringent type of device marketing application. This finding is in line with the papers by Pellerin et al. and Peters et al., noticing that devices cleared through PMA premarket approval are less represented among recalled devices [13,14].

Recall process requires corrective actions by the manufacturers: in software-related recalls, return of the device and software update were the two most frequent actions. It should be highlighted that in one recall event, the action taken by the producer was only communication to the product specialist and branch managers, as the problem was considered "not a customer facing issue". Half of the recalls were terminated at the last follow-up, showing an effective action according to FDA.

In medical device industry, software engineering practice proved deficient in terms of safety: nowadays, software-related malfunctions and recalls are still poorly investigated in computer-assisted surgery [15]. This is the first study analyzing the software-related recalls involving hip and knee arthroplasty, from pre-operative planning to surgical implantation. The systematic recall notifications and the comprehensive updated database are the two strongest points of the study. On the other side, this study has many limitations. First, this is not a clinical study: the incidence on population and the clinical consequences of software-related recalls on patients cannot be inferred. The recalls are active actions instructed and taken by firms (sometimes initiated by FDA) when the defective devices may pose health risks: notification is not mandatory if devices are removed to improve quality or function [9]. FDA warns that these data alone are not sufficient to establish the rates of events of a device and to compare event rates between devices. The public recall data provided by manufacturers may be brief, generic and out of time: the whole recall scenario may be only partially depicted and misreporting could occur [7]. Some classifications are manufacturer-dependent (the root cause) and the definitions may be not uniform among the firms involved: moreover, classifications may change until the recall termination date. Thus, in summary, under/misreporting may have occurred in this study. Moreover, the real impact of software malfunctions cannot be inferred from the medical device recalls database

alone. The section 3060(a) of the 21st Century Cures Act (Cures Act) amended section 520 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) on December 13, 2016, changed the definition of software as medical devices: it is unlikely that the present research could have been impacted [16].

Even though this study can only assess one part of the picture (not the clinical one) about software malfunctions in computer assisted arthroplasty, software-related recalls in computer-assisted hip and knee arthroplasty were quite uncommon among all the recalls (1.6%), deemed non-life threatening and usually due to software design errors (66.6%): inaccurate lower limb alignment assessment was the most frequent reason leading to recall. The main actions taken by manufacturers were the return of the device (44.4%) or the software update (38.9%). Considering the increasing adoption of software in healthcare, implementation of risk management processes should be promoted by manufacturers and active monitoring on software available on the market should be intensively stimulated among users. Registry databases providing active surveillance would be of help in order to precociously detect software-related defective devices.

FUNDING

The authors declare that no funds, grants, or other support were received during the preparation of this manuscript.

CONFLICT OF INTEREST

The authors have no relevant financial or non-financial interests to disclose.

ETHICS APPROVAL

The ethics approval was waived due to data anonymization and public database query.

REFERENCES

1 - Hazratwala K, Brereton SG, Grant A, Dlaska CE (2020) Computer-Assisted Technologies in Arthroplasty: Navigating Your Way Today. JBJS Rev. 8(3):e0157. doi: 10.2106/JBJS.RVW.19.00157.

2 - Medical Advisory Secretariat (2004) Computer-assisted hip and knee arthroplasty. Navigation and active robotic systems: an evidence-based analysis. Ont Health Technol Assess Ser. 4(2):1-39. Epub 2004 Feb 1.

3 - Chen EA, Roof MA, Lygrisse KA, Kurapatti M, Hepinstall MS, Schwarzkopf R (2021) ICD-10 Coding Mismatch in Computer and Robotic Assisted Primary Total Hip Arthroplasty. J Arthroplasty. 36(12):3934-3937. doi: 10.1016/j.arth.2021.08.002.

4 - Wasterlain AS, Buza JA 3rd, Thakkar SC, Schwarzkopf R, Vigdorchik J (2017) Navigation and Robotics in Total Hip Arthroplasty. JBJS Rev. 5(3):e2. doi: 10.2106/JBJS.RVW.16.00046.

5 - Buza JA 3rd, Wasterlain AS, Thakkar SC, Meere P, Vigdorchik J (2017) Navigation and Robotics in Knee Arthroplasty. JBJS Rev. 5(2):e4. doi: 10.2106/JBJS.RVW.16.00047.

6 - Ferrarese A, Pozzi G, Borghi F, Marano A, Delbon P, Amato B, Santangelo M, Buccelli C, Niola M, Martino V, Capasso E (2016) Malfunctions of robotic system in surgery: role and responsibility of surgeon in legal point of view. Open Med (Wars). 11(1):286-291. doi: 10.1515/med-2016-0055.

7 - Cooper MA, Ibrahim A, Lyu H, Makary MA (2015) Underreporting of robotic surgery complications. J Healthc Qual. 37(2):133-8. doi: 10.1111/jhq.12036.

8 - Simone LK (2013) Software-related recalls: an analysis of records. Biomed Instrum Technol. 47(6):514-22. doi: 10.2345/0899-8205-47.6.514.

9 – FDA Investigations operations manual 2022, Chapter 7, Recall Activities. https://www.fda.gov/media/75263/download. Last access: 16/08/2022

10 – FDA Medical Device Recalls database. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm. Last access: 26/7/2022

11 - Open FDA, medical device recalls. https://open.fda.gov/apis/device/recall/. Last access: 25/08/2022

12 - Vajapey SP, Li M (2020) Medical Device Recalls in Orthopedics: Recent Trends and Areas for Improvement. J Arthroplasty. 35(8):2259-2266. doi: 10.1016/j.arth.2020.03.025.

13 - Pellerin C, Adamson M, Janney C (2020) Recall Rates of Total Knee Arthroplasty Devices Are Dependent on the FDA Approval Process. Cureus. 12(8):e9744. doi: 10.7759/cureus.9744.

14 - Peters W, Pellerin C, Janney C (2020) Research: Evaluation of Orthopedic Hip Device Recalls by the FDA from 2007 to 2017. Biomed Instrum Technol. 54(6):418-426. doi: 10.2345/0899-8205-54.6.418.

15 - Connor MJ, Tringale K, Moiseenko V, Marshall DC, Moore K, Cervino L, Atwood T, Brown D, Mundt AJ, Pawlicki T, Recht A, Hattangadi-Gluth JA (2017) Medical Device Recalls in Radiation Oncology: Analysis of US Food and Drug Administration Data, 2002-2015. Int J Radiat Oncol Biol Phys. 98(2):438-446. doi: 10.1016/j.ijrobp.2017.02.006.

16 - FDA. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/changes-existing-medical-software-policies-resulting-section-3060-21st-century-cures-act. Last access: 14/08/2022

FIGURES AND FIGURE LEGENDS

Figure 1: software design was the most common root cause for software-related recalls in the years 2017-2021

TABLE CAPTIONS

Table 1: the distribution of the software-related recalls was homogenous over the years

	2017	2018	2019	2020	2021	Total
Manufacturing/deployment	7	14	10	6	7	44 (3.9%)
Design change	11	9	12	13	11	56 (4.8%)
Change control	3	14	11	13	12	53 (4.7%)
Design	159	219	179	177	181	915 (80.8%)
Design (manufacturing process)	8	3	2	4	3	20 (1.8%)
In the use environment	12	4	10	7	1	34 (3%)
Total	200 (17.8%)	263 (23.4%)	224 (20%)	220 (19.6%)	215 (19.2%)	1122

228

229

Table 1 Click here to access/download;Table;table 1.docx

	2017	2018	2019	2020	2021	Total
Manufacturing/deployment	7	14	10	6	7	44 (3.9%)
Design change	11	9	12	13	11	56 (4.8%)
Change control	3	14	11	13	12	53 (4.7%)
Design	159	219	179	177	181	915 (80.8%)
Design (manufacturing process)	8	3	2	4	3	20 (1.8%)
In the use environment	12	4	10	7	1	34 (3%)
Total	200 (17.8%)	263 (23.4%)	224 (20%)	220 (19.6%)	215 (19.2%)	1122

Figure 1