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

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19 **Short title: Investigating Medical Device Recalls**

20

21 **DECLARATIONS**

22

23 **CONSENT TO PARTECIPATE**

24 Not applicable

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28 Data are available as supplementary materials

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33 **CONFLICT OF INTEREST**

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

35 **AUTHORS' CONTRIBUTION**

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

40 **ETHICS APPROVAL**

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

1 SOFTWARE-RELATED RECALLS IN COMPUTER-ASSISTED HIP AND KNEE ARTHRO- 2 PLASTY

3 ABSTRACT

4 Purpose

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

10 Methods

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

14 Results

15 18 recall numbers could be identified (1.6%), corresponding to 11 recall events. 4634 units were involved.
16 The FDA determined root causes were: software design (66.6%), design change (22.2%), manufacturing de-
17 ployment (1, 5.6%), design manufacturing process (5.6%). Among the manufacturers' reasons for recalls, a
18 specific error was declared in 16 cases (88.9%). In 7 cases (43.8%), a coding error about lower limb align-
19 ment assessment was identified. 17 software-related recalls (94.4%) were classified as class 2, only one case
20 class 3 (5.6%). Return of the device was the main action taken by firms (8, 44.4%), followed by software up-
21 date (7, 38.9%).

22 Conclusion

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

26 **KEYWORDS:** medical device recalls database; malfunction; health information technology; robotic; navi-
27 gation; software design

28 **DATA AVAILABILITY:** data are available as supplementary material

29 **LEVEL OF EVIDENCE: IV**

30 **MAIN TEXT**

31 INTRODUCTION

32 Computer-assisted arthroplasty was developed to help the surgeons improve the precision, the tissue han-
33 dling, the velocity and the reproducibility of the procedure [1,2]. These theoretical advantages led to a more
34 widespread adoption of computer-assisted arthroplasty among hip and knee arthroplasty procedures: in 2015,
35 computer-assisted technologies were involved in 11.6% of all the total knee arthroplasties and 5.2% of all the
36 total hip arthroplasties, according to the New York Statewide Planning and Research Cooperative System
37 [3].

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

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

54 METHODS

55 The Medical Device Recalls database is a Food and Drug Administration (FDA) database collecting data
56 about defective medical devices on the US market subjected to recall procedures since November 2002 [9].
57 Devices are considered defective when adverse effects and potential health risks are identified and attributed
58 to the use of the device (when a device is misbranded or adulterated) [9]. A recall occurs when the manufac-
59 turer takes a removal or correction actions (excluding market withdrawal, stock recovery, safety alert) of a
60 marketed defective product that FDA considers violating the Federal Food, Drug and Cosmetic Act or might
61 require a legal action. The malfunction is usually identified by the manufacturers and notified to FDA within
62 10 working days. Even FDA itself may identify defective devices after inspection or warnings, when prod-
63 ucts may cause harms and pose risks to the public health: in this case, FDA may issue a “medical device no-
64 tification order”. The manufacturer provides data about the malfunctioning device, the description of the
65 event, the harms or the injuries that have occurred, the root cause, the actions taken and the recall strategy.

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

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

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

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

88 A descriptive statistical analysis was conducted.

89 The institutional board review was waived due to data anonymization.

90 **RESULTS**

91 1122 software-related recalls were identified between 1st January 2017 and 1st January 2022. Out of them,
92 915 recalls (80.8%) were due to software design [FIGURE 1]. The distribution over the time was detailed in
93 the table [TABLE 1].

94 **Incidence**

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

99 All the recalls involved 4634 units: a mean value of 272.6 units was involved in every recall number (range:
100 1-3232, one recall was not available). 17 software-related recalls out of 18 (94.4%) involved products dis-
101 tributed worldwide.

102 Root cause

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

105 Among the manufacturer root cause, all but two cases (16/18, 88.9%) declared a specific error. In 7 cases
106 (7/16, 43.8%), a coding error jeopardizing the lower limb alignment assessment was identified. In 2 cases
107 (2/16, 12.5%), software discrepancies not showing all the constants were traced. All the other causes oc-
108 curred once (1/16, 6.3%): inadequate image resizing and inaccurate measurements, miscalculation of femoral
109 resection depth, digital templates with incorrect files, software crash, problems with destination server,
110 wrong data loading, incorrect unit of measure for femoral cut measurements.

111 17 software-related recalls out of 18 (94.4%) were classified as class 2: only one case (5.6%) was class 3. 7
112 recalled devices (38.9%) were cleared through the PMA premarket approval, 11 ones (61.1%) through the
113 510(k) premarket notification process.

114 Actions taken due to recalls

115 Return of the device was the main action taken by firms (8 cases, 44.4%), followed by software update (7,
116 38.9%). In two cases (11.1%), the only action taken was communication to the product specialist and branch
117 managers (the problem was considered “not a customer facing issue”). In one case (5.6%), a strategy of com-
118 munication and advice about use modifications was adopted. At the time of the analysis, 10 recalls out 18
119 (55.5%) were terminated. The mean time from notification to termination was 204 days (range: 1-696 days).

120 **DISCUSSION**

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

126 According to the FDA database, the orthopaedic specialty is the main contributor to medical device recalls
127 (15%) nowadays, with software related recalls accounting for only a small part of them (around 2% of all the
128 orthopaedic recalls in 2015-2019) [11,12]. This study demonstrated that software related recalls in computer-
129 assisted arthroplasty rarely occur in the last 5 years (1.6% of all the software recall numbers in 2017-2021,
130 with 11 recall events identified). However, more than 4000 units were ultimately involved, worldwide. Soft-
131 ware-related malfunction is an emerging issue: the progressive diffusion of computer-assisted surgery (more

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

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

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

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

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

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

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183 **CONFLICT OF INTEREST**

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

185 **ETHICS APPROVAL**

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

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222 [medical-software-policies-resulting-section-3060-21st-century-cures-act](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

223 **FIGURES AND FIGURE LEGENDS**

224 Figure 1: software design was the most common root cause for software-related recalls in the years 2017-
225 2021

226 **TABLE CAPTIONS**

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

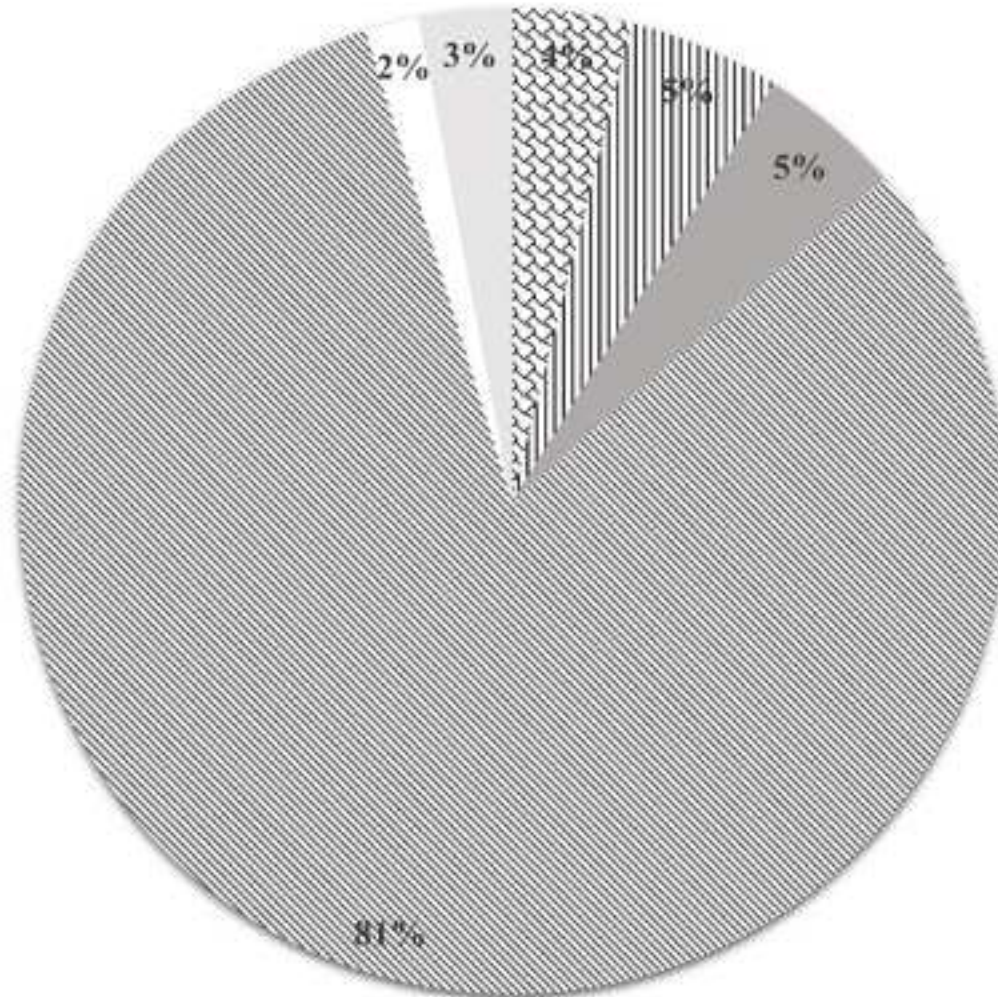
	2017	2018	2019	2020	2021	Total
Manufacturing/deployment	7	14	10	6	7	44 (3.9%)
Design change	11	9	12	13	11	56 (4.8%)
Change control	3	14	11	13	12	53 (4.7%)
Design	159	219	179	177	181	915 (80.8%)
Design (manufacturing process)	8	3	2	4	3	20 (1.8%)
In the use environment	12	4	10	7	1	34 (3%)
Total	200 (17.8%)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

228

229

	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%)
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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

Software-related recalls classification



↙ Manufacturing/deployment

|| Design change

■ Change control

⊗ Design

Design (manufacturing process) = In the use environment