Key Performance Indicators at manufacturing workflow in specific medical devices: A Systematic Literature Review

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Abstract.

In the health sector, specifically by facture treatment, it is fundamental to understand clinical and technical requirements to provide a specific solution for patients and surgeons, mainly on complex procedures. But the human resource is dynamic in both, industrial an academical sectors. Usually, the knowledge has been constructed on iterative processes trough multidisciplinary approach that involve surgeons and designers. But often, collaboration work is conducted without conscious about metrics which could provide historical performance. This is essential to provide feedback in the process, to propose improvements, and also to enhance traceability and learning skills. In our context, it is crucial because of the need to provide affordable solutions by using scare resources. To start the design of a suitable strategy which faces those aims, first, we conducted a systematic review related to reported cases. We focusing on works were technological resources and multidisciplinary collaboration was essential for specific device development. A bibliometric study was conducted with 421 documents from PubMed and Web of Science. Then, 51 documents were selected to be exhaustively review, in order to understand patterns about performance. Finally, 5 documents were identified by snowball specifically related to Key Performance Indicators on different sectors where PLM strategy was applied, summarizing 169 KPIs. As a conclusion, the authors recommended implementing 8 KPIs in medical device development.

Keywords: Additive manufacturing, collaboration, key performance indicator, specific medical devices.

1. Introduction

Morbidity rates are increasing according to the WHO, thus non-transmissible illness will represent 60% of traumas by 2020 (WHO, 2017). Healthcare cost will be a fiscal burden by 1 to 3% in GDP in many countries, mostly by traffic accidents. MD have been produced mostly for fracture treatment, oncology or congenital issues. Trauma affects the youngest adults by traffic or labor accidents, and the oldest for failings, demanding high healthcare burden. Although epidemiologic data depends on local registers, cranial contusions have prevailed from 33% to 47% of all cases (Alberdi, García, Atutxa, & Zabarte, 2014). Normally, bone resection must be performed intraoperatively as a part of a treatment, to restore bone function, fracture reduction and aesthetic. As well as traumatic defects, oncology and congenital defects could affect bone structures. So, physicians have the challenge to do restauration accurately as possible, preserving unaffected tissue and organs. For improving medical praxis and reducing mistakes, they need technical aids called medical devices MD to translate their planning to the operating theater.

Despite MD are a vast sort of artifacts (Santos, Gazelle, Rocha, & Tavares, 2012), our interest lies upon orthopedic MD and how that objects could be properly done. Orthopedic restauration could be done by a craft bone from a cadaveric donor, by autologous bone using vascularized tissue from the patient´s body, or a synthetic implant if a large defect is involved (Logeart-Avramoglou, Anagnostou, Bizios, & Petite, 2005). Usually Physicians use 2D images from computed tomography CT to diagnosis. But, 3D conversion and design with computer-aided techniques CAx (Salonitis & Stavropoulos, 2013) have been adopted as valuable tools to reduce uncertainty.

Thus, is possible to define surgical steps previosly, and fabricate patient-specific MD such as biomodels, cutting-drilling guides, and patient-specific implants PSI (FDA, 2018) by means of rapid prototyping RP, using sustractive or additive manufacturing SM–AM. Many alternatives are available, but depending on the context those are not affordable. Altough the USA and Europe drive the global market, countries like Mexico and Brazil have reported an increasing in MD fabrication(Maresova, Penhaker, Selamat, & Kuca, 2015). That is because MD produced by the scale in developed countries are not suitable for specific population needs (WHO, 2003) enhancing the need to improve quality control and technology appropriation, which represents a great opportunity for developing countries (Ishengoma & Mtaho, 2014).

On the other hand, results that fit user's requirements are possible just for multidisciplinary collaboration (Larsson et al., 2003), despite the kind or cost of tools involved. In this case, deeplly understanding of surgeon needs could save a lot of effort.

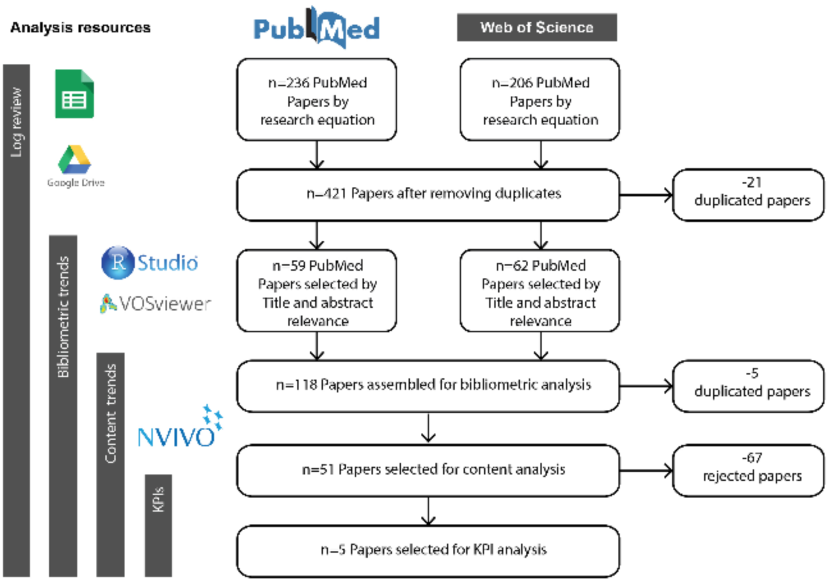
Thus, to achieve product requirements is essential to control the MD development (Hieu et al., 2010). Collaboration depends on skills shared by the team. To make accurate decisions, somo methods like Product life-cycle management PLM has shown relevance. PLM focus on governing technical documents, roles, stages, and tools by assuring integration, control, security, and traceability of data (Lantada & Morgado, 2013). Thus, a workflow compromises people and resources to control inputs/outputs. That could be measure by key performance indicators KPIs (Cable, Hoc, & Management, 2005), metrics asociated with a process that stablish a baseline to follow up. But first, it is necesarry to identify them.

To face those problems, a systematic literature review was conducted in order to identify key performance indicators KPIs, focusing on data related to the process of specific patient treatment by using technology. Following sections describe the methodology, results, and final conclusions.

2. Methodology

To proceed with the systematic review, a bibliometric analysis was conducted, then a content analysis and finally a snowball process to identified the KPIs. The entire procedure is related in **Figure 1**. Two questions were formulated to be solved: which key performance indicators related whit cost, time and quality could allow manufacturing capabilities in specific MD development? And there is a consensus about workflow? First, an exploratory thesaurus list was constructed looking for non-covered reviews for terms like “3D printing, “KPI”, and“workflow” on Prospero database (Booth et al., 2012).

Figure 1: The review process.



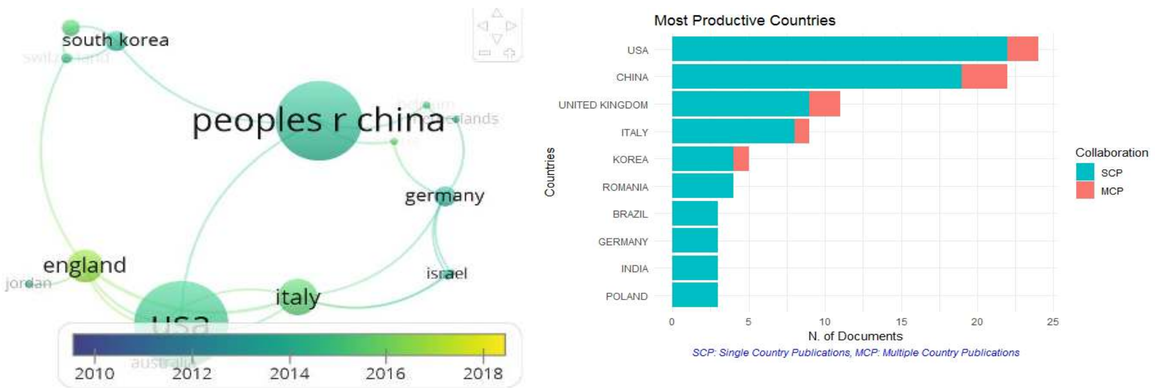
Source: By authors.

Thus, a research equation was designed by 370 different terms related to “3D printing”(24),“capability(6),“Manufacturing”(32),“collaboration”(20),“strategy”(24),“workflow”(60),“KPI”(66),“interoperability”(51),“trauma”(21),“device performance”(31), and “specific-medical device”(35). To avoid bias, anatomical zones were excluded from the research equation. Please see **table 2**, in **Appendix I**, which showed the constructed research equation. Two databases were selected due to their content quality papers, PubMed and Web of science. As inclusion criteria, only the papers written in English were selected, with content that showed quantitative or qualitative evidence in clinical trials for MD, published from 2010 to 2018. Papers non-related with clinical trials were excluded as well as literature reviews, reports, and book chapters.

3. Results

Papers excluded in the title and abstract review were related to animal treatment, surgery protocols, bioprinting, tailored instruments, splints, cardiology and ophthalmology implants. To perform data analysis, results from both database were assembled, to use it as input for Vosviewer tool (van Eck & Waltman, 2010) and bibliometrix (Aria & Cuccurullo, 2017). In the first, clustering showed relevance from China and the USA as showed in **Figure 2**. In the second, a lokta distribution was observed in the sample, with a β=3,8 and a p-value=0,21 for the Kolmogorov-Smirnoff test.

Figure 2: Most productive countries in the field.



Source: By authors.

For the content review, being N=118 papers, with a confidence level of 95% and the margin of error of 10%, the sample size calculated was 51 papers. Papers related to esthetical implants, non-osseous implants, and old samples were omitted. Those papers were analyzed with Nvivo v12. Rather than previous results, 24 author's nationalities were observed, 23,5% were from China, 11,8% form Italy, 7,8% from the United Kingdom, just 3,9% from the USA, and 2% from Mexico. Those papers were mostly reported practical content 76%, theoretical 18% and theoretical-practical 6%.

Figure 3. Clinical case frequency by anatomical zone.

Source: By authors.

Study cases samples varied from 1 to 31 people, with an average age from 3 to 65 years, mostly by women 56%. The sample etiology was mostly due by trauma 36%, following by oncology pathologies 34%, congenital defects 28% and arthrosis 2%. Institutions characteristics were labeled as university hospital 33%, hospital 16 %, university 47%, and military hospital 4%. Researches were conducted mostly by a department of cranio-maxillofacial surgery. That showed consistency for anatomical zone affected for pathology, mostly cases in the skull by 82,5%, as showed in **Figure 3**.

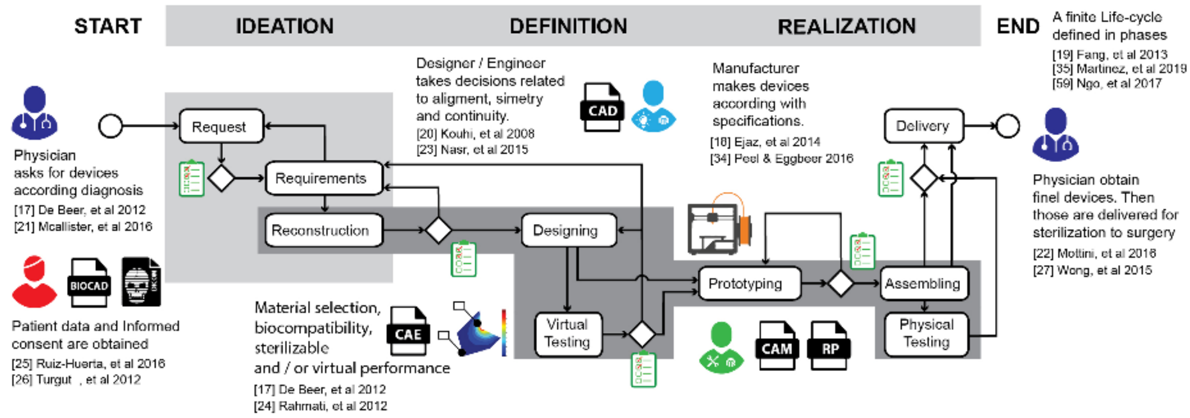
Also was observed the kind of MD reported. Virtual surgical pre-planning was conducted in 94,1%. A physical biomodel was required in 66,7%. Permanent implants were setting on 52,9% of cases. A surgical guide was used in 43,1%. Position guides were both used in 13,7%. Technology integration was observed as well to help accelerating process. BIOCAD, CAD, and RP by AM were used in 94,1% cases. Reverse engineering RE was observed just by 27,5%.

Computer aided engineering CAE analysis by 15,7%. Computer aided manufacturing CAM by SM in 11,8%. BIOCAD was commercial software in 72,5% of cases, open software in 13,8%, and own development software by 3,9%. Commercial CAD software was used by 49%, educative licenses by 19,6%, and open software by 7,8%. RE software help designer to fix the virtual mesh, but just 9,8% reported its. Similarly, CAE software was used by 9,8%. To manufacturing devices, by SM means, were reported molding 13,7%, polishing 9,8%, bending 9,8%, CNC 7,8%, casting 7,8%, and sculpting 5,9%. By AM means, metal printing DMLS-SLS leads trend with 41%, following for photo-polymeric resin that was used in 29%, polymeric thread FDM by 22%, and ceramic printing 3DP-BJ by 14%.

4. Discussion

Some authors reported a formalized workflow (Beer, 2013; Ejaz et al., 2014; Fang, Liu, Wu, Lee, & Kuo, 2013; Kouhi, Masood, & Morsi, 2008; McAllister, Watson, & Burke, 2018; Mottini, Seyed Jafari, Shafighi, & Schaller, 2016; Nasr, Al-Ahmari, Alkhawashki, Altamimi, & Alkhuraisi, 2015; Rahmati, Abbaszadeh, & Farahmand, 2012; Ruiz-Huerta, Almanza-Arjona, & Caballero-Ruiz, 2016; Turgut, Özkaya, & Kayal, 2012; Wong, Kumta, Gee, & Demol, 2015). Authors reported its interest on virtual modelling (Bogu, Ravi Kumar, & Khanara, 2017; Egger et al., 2017), steps for virtual reconstruction and manufacturing (Ciocca et al., 2015; Han et al., 2017; Nasr et al., 2015; Park et al., 2016), clinical process (Mazzoni, Bianchi, Schiariti, Badiali, & Marchetti, 2015; Mottini et al., 2016), in-house capabilities (McAllister et al., 2018), and comparison between conventional and digital workflow (Peel & Eggbeer, 2016; Ruiz-Huerta et al., 2016). Despite there is not a consensus about the workflow, we proposed one, based on the steps following by decisions in each phase of the life-cycle for MD development (Martiínez, López, Murillo, & Garnica, 2019). Workflow is showed in **figure 4**. Next, the finding related to quality, cost and time was summarized.

Figure: 4. a common workflow observed in the literature review.



Source: By authors.

4.1. Manufacturing Capabilities

Quality was commonly related after surgery to measure sensibility of pain (Cassetta, Altieri, Pandolfi, & Giansanti, 2017; Hussein, 2013), symmetrical contour (Azuma et al., 2014; Hatamleh, Yeung, Osher, & Huppa, 2017), patient and surgeon satisfaction (Kanno et al., 2016; Ortiz et al., 2012), aesthetics (Chrzan et al., 2012; Kaur et al., 2015), infection rate diminution (Park et al., 2016; Turgut et al., 2012), blood loss (Mendez, Chiodo, & Patel, 2015; Wei, Guo, Ji, Zhang, & Liang, 2017), functional recovery (Xu et al., 2016; Y. Zhang et al., 2018) and virtual comparison from virtual preplanning to result (Abdel-Moniem Barakat, Abou-Elfetouh, Hakam, El-Hawary, & Abdel-Ghany, 2014; Yang et al., 2018; L. Zhang, Shen, Yu, Shen, & Wang, 2015).

Some authors reported cost depending on their interest. A biomodel could be fabricated by less than 300 € (Kozakiewicz et al., 2009). Surgical guides for maxilla and biomodel cost would be 500 to 1000 € (Mazzoni et al., 2015). Implants, of course, are more expensive. An orbital implant could cost 2,000 to 14,000 USD$ (Callahan, Campbell, Petris, & Kazim, 2017). An skull implant could cost 300 to 1300 USD$ (Chrzan et al., 2012) or 800 USD$ (Goh, Chang, Lin, & Lo, 2010). A mandible implant could cost 1500 to 3000 € (Gil et al., 2015), or 5000 to 7000 USD$ (Ruiz-Huerta et al., 2016). Some authors compared inner with outsourcing cost. Thus, that could be reduced from 2000 to 1000 £ (McAllister et al., 2018), from 1782 to 660 £ (Peel & Eggbeer, 2016) or 4000 to 25 USD$ (Mendez et al., 2015).

Time as well depends on the author's interest. Comparing conventional techniques to RP, total treatment was reduced from 24 to 8 months (Cassetta et al., 2017), 7 to 6 days (Peel & Eggbeer, 2016), even less than 48 hours (Mottini et al., 2016). Other looking for a reduction of intraoperative time (Chrzan et al., 2012) or saving time for use biomodels to pre-bent plates (Reiser et al., 2015). Other were focusing on time segmentation by BIOCAD, 2 hours average (Egger et al., 2017). However, exist drawbacks when metallic noise is on CT, taking between 18 to 22 hours per case (Kouhi et al., 2008). Although design time, 8 hours, could be less than manufacturing, 25 hours (Rahmati et al., 2012), other author reported that the entire project could be longer, 3 to 36 days, depending on complexity (McAllister et al., 2018), or 2-3 weeks by outsourcing and delivery (Mendez et al., 2015). Although development and design

time could be less than 30 hours, delivery could last 3,4 weeks (Yang et al., 2018) or 5-10 weeks if the request was into a developing country (Ruiz-Huerta et al., 2016).

4.2. PLM in the Health sector

In the systematic review conducted, the use of PDM software was observed in just 3,9% of all cases. Despite benefits that PLM have promoted in different industrial sectors, is relative rare its implementation in the health sector. Zdravković, Trajanović, Stojković, Mišić, & Vitković, 2012 identified interoperability as a crucial factor to reduce time and errors in PSI development. Allanic et al., 2015 proposed a commercial PDM implementation for an imaging laboratory with a lot of heterogeneous data and different roles involved. Popescu, Ilie, Laptoiu, Hadar, & Barbur, 2016 had reported an ongoing web-based platform to support communication between actors in a PSI cranial treatment. Finally, Ngo, Belkadi, & Bernard, 2017, had formulated a PLM framework to support PSI development, keep data safely and support different roles involved in a workflow.

4.3. KPI to control the process

There are so many variables to take into account. But was necessary to identify them to set its relevance. However, it is recommended for management that the quantity of KPI might be between 7 to 12, grouped in 4 to 8 categories (Lavy, Garcia, & Dixit, 2010). Just one paper, Peel et al (Peel & Eggbeer, 2016) explicit mentioned KPI related to process development on PSI. They have identified 3 different manufacturing strategies for PSI fabrication, namely conventional, semi-digital and digital, comparing workflows, cost and time. It was proposed 41 KPIs, but, 3 mainly KPIs were highlighted: the number of design changes, fidelity on specifications, and routine adoption rate. Other authors explored by snowball were identified in different sectors. Alemanni et al (Alemanni, Alessia, Tornincasa, & Vezzetti, 2008) proposed 47 KPIs for aerospace development grouped on 5 categories. Myung et al (Myung, 2018) projected 20 KPIs for naval design grouped in 3 categories. Stark (Stark, 2016) suggested 36 KPIs grouped in 4 categories in PLM implementation. Finally, Pinna et al (Pinna et al., 2018) advocated using 25 KPIs in the Food industry grouped in 4 categories. In total, 169 KPIs were analyzed and codified. Thus, in **table 1**, we proposed the most suitable KPIs to taking into account.

Table 1. Summary for KPIs proposed.

Category	KPI	Description
Time	2	Developed time. From CT acquisition to surgical date. From CT arrive at medical device delivery.
Cost	1	Developing cost. The human resources, material and machine expenditures in a case.
Quality	5	The number of changes in a project. The percentage of requirement accomplished. Surgeon satisfaction. CT resolution. 3D print resolution.

Source: By authors.

5. Conclusion

First, the systematic literature review allowed us to understand the different technological integrations that researchers have adopted during the design and development of specific MD such as biomodels, surgical guides, and implants, specifically for traumatic, oncology a congenital defects. Second, patterns about MD interest and tools integration showed RP importance in the field, been AM more adopted than SM. Third, PLM in health sector, regardless complexity of implementation, it would be a gap to explore in the health sector. Third, KPIs related to management capabilities, like delivery time, cost and quality have been observed in the MD process.

Even though some parameters in design could be an input for KPIs, like material mass for overall cost, the difference lies that KPIs are associated with corporative measurable goals, in order to monitoring causes and take decisions based on historical data from cases. Thus, based on the KPIs identified, we proposed 8 KPIs grouped on 3 categories to support metrics in specific MD development. Results will be applied in further works to define metrics in a PLM strategy for orthopedic treatment that depends on team work.

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Disclosure

The authors report no conflict of interest for economic, ethical or social topics in the present paper.

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Appendix I.

Table 2: The Log review and research equation.

No	Sub-research equation group	WOS results	PubMed results
#1	TS=("3D print*" OR "3-dimension* print*" OR "3-D print*" OR "three dimension* print*" OR "additiv* manufactur*" OR "AM" OR "additive technolog*" OR "rapid prototyp*" OR "RP" OR "prototyp* 3D print*" OR "desktop manufactur*" OR "desktop 3D print*") *Data bases= WOS, KJD, RSCI, SCIELO. Time period=2010-2018. Language=English*	150,774	1,596,013
#2	TS=("manufact* capab*" OR "operat* capab*" OR "technolog* capab*" OR "manufact* estrateg*" OR "product develop*" OR "conventional fabrication" OR "substrative manufact*" OR "traditional technolog*" OR "CNC" OR "computer-integrated manufact*" OR "milling" OR "digital fabrication" OR "direct digital manufact*" OR "CAD" OR "computer-aided design*" OR "manufact* informat* system*" OR "stage*" OR "process*"OR "pre-process*" OR "post-process*") *Data bases= WOS, KJD, RSCI, SCIELO. Time period=2010-2018. Language=English*	4,835,004	2,447,578
#3	#2 AND #1	39,445	116,716
#4	TS=("collaborat*" OR "collaborat* software" OR "collabor* work*" OR "collabor* strateg*" OR "work* together" OR "collabor* framework" OR "collabor* model" OR "collabor* situation*" OR "teamwork*" OR "joint effort" OR "cooperat*") *Data bases= WOS, KJD, RSCI, SCIELO. Time period=2010-2018. Language=English*	373,293	73,711
#5	TS=("strateg*" OR "detail* plan*" OR "blueprint*" OR "itinerary" OR "long-range plan*" OR "operat* strateg*" OR "guideline" OR "implement*" OR "PLM" OR "product lifecycle manage*" OR "lifecycle phase*" OR "traceability" OR "data security" OR "role*" OR "action course*" OR "progress monitor*") *Data bases= WOS, KJD, RSCI, SCIELO. Time period=2010-2018. Language=English*	3,778,186	2,583,251
#6	TS=("workflow" OR "digital workflow" OR "clinical decision mak*" OR "conventional workflow" OR "wait* time*" OR "delivery" OR "best practice*" OR "engag* service*" OR "organiz* process" OR "stage* process" OR "role" OR "role identi*" OR "actor*" OR "heterogene* expert*" OR "specific NEAR/2 patient*" OR "radiologist*" OR "medical doctor*" OR "physician*" OR "plastic surgeon*" OR "orthopedic surgeon*" OR "nurse*" OR "industrial engineer*" OR "industrial designer*" OR "design engineer*" OR "manufacture engineer*" OR "quality engineer*" OR "treatment process" OR "BMP" OR "business process model" OR "UML" OR "unified modeling language" OR "flow chart" OR "delivery priority" OR "peer-to-peer" OR "P2P") *Data bases= WOS, KJD, RSCI, SCIELO. Time period=2010-2018. Language=English*	2,718,886	3,379,536
#7	TS=("KPI" OR "key performance indicator*" OR "key performance parameter*" OR "key characterist*" OR "health resource*" OR "health manpower" OR "performance employee" OR "performance activit*" OR "performance process*" OR "measur*" OR "test*" OR "metric*" OR "rat*" OR "measur* progress*" OR "measur* performance" OR "amount" OR "work* performance" OR "device parameter*" OR "device key indicator*" OR "test* requirement*" OR "cost reduction" OR "time reduction" OR "expect* time" OR "quantity of material" OR "available material" OR "custom procedure" OR "quality control" OR "final comparison" OR "cleanliness" OR "damage check*" OR "speed" OR "resolution" OR "accuracy" OR "reliability" OR "repeatability" or "smooth") *Data bases= WOS, KJD, RSCI, SCIELO. Time period=2010-2018. Language=English*	9,594,516	4,132,607
#8	TS=("Interoperab*" OR "health information exchang*" OR "health information system*" OR "healthcare" OR "barrier*" OR "facilitator" OR "information storage" OR "health information interoperab*" OR "health information system interoperab*" OR "technolog* integrat*" OR "product data manag*" OR "neutral exchang*" OR "data shar*" OR "information shar*" OR "storage data" OR "main data" OR "data access right*" OR "imag* data" OR "DICOM standard" OR "disease data" OR "imaging data" OR "STL file*" OR "updat*" OR "synchroni*" OR "heterogeneous tool*") *Data bases= WOS, KJD, RSCI, SCIELO. Time period=2010-2018. Language=English*	938,392	1,270,238
#9	#8 AND #7 AND #6 AND #5 AND #4	3,568	649
#10	TS=("trauma*" OR "wound*" OR "injur*" OR "external force" OR "structural disruption" OR "continuity disruption" OR "bone fractur*" OR "rupture" OR "surgical" OR "orthopedic" OR "arthroplasty" OR "severe injur*" OR "violent attack" OR "accident" OR "damage" OR "harm") *Data bases= WOS, KJD, RSCI, SCIELO. Time period=2010-2018. Language=English*	2,086,851	2,438,294
#11	TS=("medical device*" OR "device performance" OR "economic evaluation" OR "technology assessment" OR "device performance" OR "device quality" OR "custom* device" OR "personal*	1,860,793	2,191,233

No	Sub-research equation group	WOS results	PubMed results
	device" OR "tailored device" OR "requirement accompli*" OR "biocompatib*" OR "time reduc*" OR "safety" OR "efficacy" OR "effectiveness" OR "aesthetic" OR "recovery time" OR "post-surgery" OR "blood loss" OR "steril* material" OR "compliance") *Data bases= WOS, KJD, RSCI, SCIELO. Time period=2010-2018. Language=English*		
#12	TS=("Specific Medical devices" OR "pre-surgical planning device" OR "educati* device*" OR "biomodel device" OR "cut* guide*" OR "surgical guide*" OR "implant" OR "patient-specific implant" OR "PSI" OR "surgical tool*" OR "prosthetic" OR "temporary prosthesis" OR "3D print* medical device" OR "non-3D-print* medical device" OR "anatomical model*" OR "segment*" OR "relevant region" OR "osteotomy alignment ") *Data bases= WOS, KJD, RSCI, SCIELO. Time period=2010-2018. Language=English*	419,302	1,628,573
#13	#12 AND #11 AND #10	17,810	65,385
#14	#13 AND #9 AND #3	0	1
#15	#13 AND #3	192	466
#16	#13 AND #9	3	4
#17	#9 AND #3	11	20
#18	#17 OR #16 OR #15	**206**	488
#19	(((#14) OR #15) OR #16) OR #17 AND *("2008/09/07"[PDat] : "2018/09/04"[PDat] AND "humans"[MeSH Terms] AND English[lang])*	-	236

Source: By Authors. Sub-research equation were written like this: "TS=(...)" defined for Web Of Science, and "search(...)" for PubMed. Filters used in both were showed in italic.