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Patient-specific instruments: industry's innovation with a surgeon's interest

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Abstract
Purpose The aim of this study was (1) to survey the orthopaedic companies about the volume of patient-specific instruments (PSI) used in Europe and worldwide; (2) to survey a group of knee arthroplasty surgeons on their acceptance of PSI and finally; (3) to survey a medico-legal expert on PSI-related issues.
Methods Seven orthopaedic implant manufacturers were contacted to obtain their sales figures (in volume) of PSI in Europe and worldwide for the 2011 and 2012 period. During the Open Meeting of the Belgian Knee Society, a survey by a direct voting system was submitted to a selection of knee surgeons. Finally, a number of medico-legal 'PSI-related' questions were submitted to an adult reconstruction surgeon/legal expert.
Results The total volume, for all contacted companies, of PSI in Europe for 2012 was 17,515 total knee arthroplasty (TKA) and 82,556 TKA worldwide. Biomet (Warsaw, USA) was the number one in volume, both in Europe as worldwide with their Signature system. Biomet represented 27 % of the market share in PSI worldwide. Stryker preferred not to reply to the survey because of the FDA class 1 recall on ShapeMatch cutting guides. Eighty per cent of the Belgian knee surgeons expressed a great interest in PSI and especially, for 58 % of them, if it would increase their surgical accuracy. They valued it even more in unicompartmental arthroplasty, and 55 % was ready to use single-use instruments. Surprisingly, 47 % of surgeons thought it was the company's responsibility if something goes wrong with a PSI-assisted case. The medico-legal expert concluded that PSI is a complex process that exposes surgeons to new risks in case of failure and stated that companies should not produce surgical guides without validation of the planning by the surgeon.
Conclusion Patient-specific instruments is of great interest if it can proof to increase the surgical accuracy in knee arthroplasty to the level surgeons are expecting and if in the same time it would make the surgical process more efficient.
Level of evidence V.

Keywords Total knee arthroplasty · Patient-specific instruments · Accuracy · Medico-legal · Survey study

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Introduction

Orthopaedics, and especially knee arthroplasty, is accompanied by cycles of innovation [16, 53]. Surgeons, looking for better results for their patients, can drive this innovation

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as it was the case with the minimal invasive approaches [1, 45, 46], or it can be driven by the industry who wants to differentiate themselves from their competitors or make the surgical process more cost efficient [30]. Surgeons should always be involved and be practical during the introduction of innovation by comparing potential risks and benefits for patients [13, 29]. Often, innovation depends on new technologies and comes at a cost [44]. These new technologies can be inventions coming from engineers making tools available that did not exist before. I-pads (Apple, Cupertino, CA, USA) can be used today to measure pivot shift behaviour of the knee or as a simple navigation tool during total knee arthroplasty (TKA) [17, 32].

Since the basic design of TKA is not going to be changed drastically in the next few years, the classic product cycle around this business is focusing on the processes for TKA implantation. The latest product cycle was aiming at improving the accuracy of the knee arthroplasty procedure. Engineers have developed a software program that makes it possible to turn two-dimensional CT or MRI images into three-dimensional representations of the human anatomy (Mimics, Materialise, Leuven, Belgium) [24]. On these 3D images and/or the CT/MRI, the anatomical landmarks used to position implants can be identified with a proven intra-and inter-individual accuracy [49]. With this technique, an advanced 3D planning of the three planes and six degrees of freedom of the knee implant is performed. The 3D planning is then transferred via patient-specific instruments (PSI) that fit the knee surfaces of the individual patient to make it reproducible during surgery [24–26, 31].

Prospective randomized studies about PSI are scarce today [6, 37, 48], and an important marketing campaign by the companies made the guides available to surgeons all around the world. The orthopaedic community is waiting eagerly for outcomes on PSI, about the variable alignment results and potential errors of this technology. Interested about the impact of the companies marketing, a survey study was designed.

In this study, a survey about three domains of PSI was done on (1) the number of PSI cases performed in Europe and worldwide by the major orthopaedic companies that made their sales figures available; (2) the opinion of 45 knee surgeons attending the annual Open Meeting of the Belgian Knee Society; and (3) the advice of a surgeon/medico-legal expert on PSI-related issues.

Materials and methods

Senior management within the main orthopaedic companies was contacted by mail with the question to share with us their volume of PSI-assisted cases for 2011 and 2012. These numbers should cover both TKA and unicompartmental arthroplasty (UKA), if offered by their company. The seven included companies were by alphabetical order, Biomet (Warsaw, USA), DuPuy-Synthes (Warsaw, USA), Medacta (Castel San Pietro, Switzerland), Smith & Nephew (Memphis, USA), Stryker (Mahwah, USA), Wright Medical (Memphis, USA) and Zimmer (Warsaw, USA). Stryker preferred not to answer because of the FDA class 1 recall on their ShapeMatch cutting guide. The responding companies were also asked to provide intra- and inter-observer accuracy for determining the surgical epicondylar axis (SEA), defined as the sulcus on the medial epicondyle and the highest point on the lateral condyle [49], of their planning engineers as well as their average and best lead time (for exceptions) and the average selling price for PSI guides in Europe.

During the Belgian Knee Society Open Meeting in November 2012, which was well attended by 82 surgeons, a direct surgeon survey was performed on a group of 45 knee surgeons with a direct voting system. Surgeons received 10 different multiple-choice questions, and they had 10 s to reply to the question. Results were only shared with the audience later on during the evening, to not influence them on the next question.

Finally, during that Open Meeting of the Belgian Knee Society, a presentation was given by an adult reconstruction surgeon who is also a medico-legal expert (HD). A few key questions were proposed to the medico-legal expert before the meeting, and he had prepared the answers and presented his findings in front of the assembly.

Results

The number of performed PSI cases is ranked by alphabetical company order, in two tables for 2011 and 2012. Table 1 represents the results for TKA in Europe and worldwide and Table 2 for UKA in Europe and worldwide, if offered by the company. On average, there was a global increase in PSI utilization for TKA by a factor 1.5 times between 2011 and 2012. Results for UKA are too

Table 1 Numbers in volume PSI TKA cases 2011 and 2012

Company name by alphabetical order	PSI TKA Global 2011	PSI TKA Europe 2011	PSI TKA Global 2012	PSI TKA Europe 2012
Biomet	11,192	3,169	22,506	6,501
DuPuy-Synthes	6,000	700	16,000	1,100
Medacta	4,600	3,400	6,200	4,600
Smith & Nephew	19,500	1,825	22,000	2,614
Wright Medical	1,600	400	2,000	550
Zimmer	9,800	1,250	13,850	2,150

Table 2 Numbers in volume PSI UKA cases 2011 and 2012

Company name by alphabetical order	PSI Uni Global 2011	PSI Uni Europe 2011	PSI Uni Global 2012	PSI Uni Europe 2012
Biomet	75	35	1,710	567
DuPuy-Synthes	Na	Na	Na	Na
Medacta	160	160	200	200
Smith & Nephew	Na	Na	Na	Na
Wright Medical	Na	Na	Na	Na
Zimmer	60	12	900	250

Na non-available

Table 3 Practical information about different PSI guides

Parameter	Average lead time in working days	Fastest lead time in working days	Average selling price (Europe)
Biomet (Signature)	20 D	3 D	500€
DuPuy (Trumatch)	30 D	15 D	450€
Medacta (MyKnee)	21 D	5 D	750€
Smith & Nephew (Visionaire)	28 D	14 D	385€
Wright Medical (Prophecy)	20 D	10 D	650€
Zimmer (PSI)	18 D	6 D	395€

preliminary to come to conclusions. Table 3 gives an overview of lead times and average selling prices in Europe. From all the companies contacted, only Medacta (Castel San Pietro, Switzerland) was ready to provide data about the intra- and inter-observer accuracy of their PSI system. The inter-observer variability of finding the SEA on CT scan was studied on five different operators and gave a SD of 0.5°, and the intra-observer variability was studied on 15 samples with a SD of 0.7° (Data on file at Medacta). The other companies considered it sensitive data for internal use only.

Table 4 resumes the 10 questions proposed to the audience during the Open Meeting of the Belgian Knee Society, and the answers are given here in this section. If not specified otherwise, the remaining surgeons out of 45 abstained by voting no opinion. The results of the voting showed the opinion of surgeons about PSI with 36/45 (80 %) considering PSI as the future and 3/45 (7 %) opposing completely to this statement. A minority of 13/45 (29 %) was ready to perform all their TKA surgery only with PSI, but 27/45 (60 %) opposed firmly to this statement. On the question if PSI increased their accuracy, 26/45 (58 %) agreed completely or partially and 15/45 (33 %) opposed firmly. The majority preferred an MRI-based system 27/45 (60 %) over a CT-system selected by 18/45 (40 %). A pinning system was preferred by 26/45 (58 %) and a cutting system by 19/45 (42 %). Patient-matched implants seemed appealing to 28/45 (62 %) but 12/45 (27 %) opposed to the idea. Single-use instruments were appreciated by 25/45 (55 %) if it made their surgery more accurate, 8/45 (18 %) if it was cheaper for the hospital, 7/45 (16 %) if it reduced the risk for infection and finally 5/45 (11 %) if it reduced the surgical time. PSI for UKA was considered added value by 26/45 (58 %), but 5/45 (11 %) opposed and 14/45 (31 %) had no opinion. Surprisingly, 21/45 (47 %) thought that if a PSI case goes wrong, it is not their responsibility; however, 19/45 (42 %) surgeons opposed to this idea. The remaining 5/45 (11 %) had no opinion on this question. On the final question if engineers were smarter than surgeons and would be better planners, 32/45 (71 %) disagreed completely and only 3/45 (7 %) agreed fully or partially.

Table 5 resumes the questions to and answers from the medico-legal expert (HD). Concerning the idea of 47 % of surgeons in this survey, that the company is responsible if a PSI-assisted case goes wrong, the expert brought an important nuance. The surgeon is always the end responsible. A grey zone could be those cases where the company produced guides without validation of the planning by the surgeon.

Discussion

The most important finding of this study was that the worldwide increase in the number of PSI-assisted cases, based on data delivered by the different companies, showed an important impact of this technology on today's knee arthroplasty market and this despite the availability of few peer-reviewed papers and an important economical cost [35, 41]. The survey among knee surgeons showed a continuous interest in PSI and especially for UKA. Finally, surgeons should be aware of new medico-legal implications by the use of PSI, and companies should avoid producing PSI guides without validation by the surgeon.

The peer-reviewed literature on PSI is for the moment still limited with only a few high-quality studies available [4, 6, 48]. The initial papers by early adopters of the technology were globally showing a mean mechanical axis comparable to conventional surgery with a lower rate of outliers in the coronal plane, but without significant difference [3, 5, 10, 18, 19, 25, 26, 34–37]. Subsequently, a few retrospective studies about Visionaire (Smith & Nephew, USA) were more critical [8, 9, 28, 46, 47, 50], and a recent randomized controlled trial, where different PSI systems were controlled with navigation during surgery, did not show convincing evidence for three-plane alignment superiority for PSI [48]. Nam et al. [33] compared PSI to navigation for the coronal plane and found

Table 4 Questions for the Belgian Knee Society assembly during voting

1.	Patient-specific instruments are the future?
2.	I am ready to perform all my TKA surgery only with PSI starting 2013?
3.	Patient-specific instruments increase my accuracy in the three planes and make me more efficient as a surgeon?
4.	I prefer an MRI-based or a CT-based system?
5.	I prefer a pinning or a cutting guide system?
6.	I would like to have patient-matched implants?
7.	I am ready to start using single-use instruments?
8.	I believe patient-specific instruments are even more indicated in unicompartmental arthroplasty?
9.	When a patient-specific instruments-assisted case goes completely wrong, it is the company's responsibility and not mine as a surgeon?
10.	Engineers are smarter than surgeons and therefore they are better planners?

Table 5 Questions and answers from the medico-legal expert

1.	Who is responsible if a PSI CT/MRI is not performed according to the guidelines?
	Answer: Radiologist
2.	What if the CT is not well performed and the planning engineers ask for a rescan?
	Answer: Discuss case with patient and let him decide if he wants to re-scan or have surgery with conventional instruments
3.	Who is responsible if a PSI-assisted case ends up with an unacceptable or unsatisfying result? Radiologist? Planning Engineer? Implant Distributor? Surgeon?
	Answer: Surgeon always end responsibility
4.	Who is responsible if PSI guides are created and delivered without validation of the planning by the surgeon?
	Answer: The company
5.	Can a company produce surgical PSI guides from the default setting without surgeon's validation?
	Answer: No they cannot
6.	Can a patient file a complaint against a surgeon because he didn't use PSI and his alignment is within the range of conventional alignment?
	Answer: Of course he can file a complaint but the guidelines for best practice today don't propose PSI as the standard of care and peer-reviewed literature doesn't support this either today
7.	Can a patient file a complaint against a surgeon because he didn't obtain neutral (180° HKA angle) after surgery?
	Answer: No, peer-reviewed literature shows that good results can be obtained, even at long term, without neutral alignment

30 % of outliers in the PSI group. There is of course a bias in the recent papers, because most are published by high-volume centres with well-experienced surgeons who are able to perform better than average with conventional instruments [4, 48]. Therefore, it would be interesting to study more often the results of the average knee surgeon, performing small numbers a year, both with PSI and conventional instruments [20]. There is also a learning curve included in the 3D planning, both for engineers and surgeons that have to validate their surgical planning. At the cradle of PSI, some decisions were taken arbitrarily to facilitate the planning process and not necessary to obtain the optimal mechanical alignment. Today, many companies have adapted and often ameliorated their surgical planning algorithms. Surgeons realize also more than ever that they need to validate the planning and that the default planning by the engineer should not just be accepted blindly. Surgeons should also have access to the data about intra-and inter-engineer planning accuracy for a device that states to improve accuracy. Therefore, surgeons should ask their PSI delivering company what their engineers accuracy is. The increasing sales volume in this survey study demonstrated nicely the impact of the marketing machine and the broad adoption of new technologies before outcome data became available.

The survey among companies showed also that the average lead time across companies to deliver a PSI guide is around 23 days and that some companies can deliver more quickly in case of exceptions. If PSI would continue to develop, a reduction in lead time would be interesting, especially for the lower volume surgeons with shorter waiting lists.

The average selling price of PSI in Europe across the six companies is 522€, with a range from 385€ to 750€. The cost of MRI/CT and the indirect cost of all the extra efforts, done by patients and surgeons, should be added to the direct cost of the guides, leading to an average total cost for PSI of about 1,200€ per case. This extra cost for technology should reimburse itself to society, either by increased operating room efficiency with shorter surgery times then

the published ±10 min today [5, 36, 38, 42], or by better alignment in the three planes, especially for younger patients expecting a long-term survival of their implant [15, 41, 51]. Today neither has been proven [4].

The results of the survey clearly show that 80 % of Belgian knee surgeons consider PSI the future and 29 % is ready to perform all their surgeries with PSI only and that despite the absence of peer-reviewed articles proving superiority for PSI over conventional instruments, the process of developing some experience with a new technique, to set up a well-designed randomized controlled trial and to have a minimal follow-up, limits the scientific world in the race against commercial statements about potential benefits of new technologies [40].

The survey also showed that surgeons are looking to combine more efficiency and accuracy in their procedure. Some articles reported about a small reduction in surgical time, but not all papers or systems confirm this [24]. An MRI-based system was still preferred by the majority of surveyed surgeons (27/45) which is understandable in the concept of avoiding radiation for their patients. However, MRI has many limitations like a longer scan time with the danger of a changed patient position, claustrophobia, no pacemaker patients allowed or too important obesity around the knee limiting the quality of the exam and in many countries a longer waiting list [24, 37]. On top of all that the MRI-based PSI systems often needed per-operative changes to correct for suboptimal depth of cuts or sizing [43].

The importance of accuracy in UKA has been well stated in the literature [7, 14, 22] and the potential for help in finding the anatomical landmarks with new technology too [21, 27, 39, 52]. The same observation was made in this survey; surgeons are open to PSI in UKA [12, 23]. Finally, surprisingly enough, 47 % of Belgian surgeons estimated that the company is responsible when PSI-assisted surgery goes wrong. Further analysis should be performed, but probably, the surgeons extended the concept of the companies responsibility for an implant to the PSI guides. The quality of the guides can be considered their responsibility, but not the surgical planning they are transferring onto the patient with the guides.

The analysis of the medico-legal expert was interesting and showed how the use of PSI exposes us to new risks. Therefore, a proven-added value should be present before exposing our patients to radiation in case of CT-based guides and for us surgeons to invest time and efforts into the practical side of handling planning and reception of PSI guides. The expert emphasizes that companies should have a validated surgical planning endorsed by the surgeon responsible for that case. If not, the production of guides and the consequences of their use during TKA could lead to the company's implicit responsibility.

A limitation of this study is the remaining question, after the sales volume analysis of the companies, if PSI was more often used by low- or high-volume surgeons [2]. This question could also be extended to the dilemma if high-volume surgeons should be the key users of PSI, since they probably understand the surgical planning better and a potential reduction in surgical time could make a difference for their surgical efficiency [11, 35]. On the other hand, if the average result of a low-volume surgeon could be ameliorated by better alignment and maybe shorter tourniquet times [20]. The type of survey performed in this study, via the companies, made it impossible to answer these questions. Further prospective studies with low- and high-volume surgeons might provide an answer to this question [43].

The importance of this study lies in the fact that it shows how increasing volume and acceptance by surgeons can be observed for new technologies before quality studies can prove the commercial statements made by developers.

Conclusion

The results of this survey study show a clear interest in PSI from the surgeon's side confirmed by the massively increasing numbers of performed PSI cases in Europe and worldwide. At this rate of new technology-based TKA implantations, proven results are quickly needed to consolidate this technique. Companies producing and delivering guides without validation of the surgeon expose themselves to medico-legal issues.

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