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ORIGINAL STUDY

The indirect cost of Patient-Specific Instruments

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Purpose : **To calculate the indirect costs of Patient Specific Instruments (PSI) based on an opportunity cost, cost of efforts and a supply chain cost model to compare PSI for value with conventional total knee arthroplasty (TKA).**

Methods : **In 81 patients the total (direct + indirect) cost of PSI-assisted TKA was compared with conventional TKA. Surgical times and coronal mechanical alignment were measured to evaluate the effectiveness of the PSI system.**

Results : **Indirect costs (459 euro) make up 40% of the total cost that can run up to 1142 euro for a patient operated with PSI guides. No difference in surgical times or coronal alignment was observed in between both groups.**

Conclusion : **Considering the total cost of PSI no value was found for the use of PSI in primary TKA as measured by surgical times or for obtaining a neutral mechanical axis in the coronal plane.**

Keywords : patient specific instruments ; indirect costs ; cost-effectiveness ; total knee arthroplasty ; economics.

INTRODUCTION

Total knee arthroplasty (TKA) is a successful procedure but a common cause of failure is still malalignment of components (*24*). A higher failure rate was observed for components misaligned in the coronal plane outside the window of 2.4° of varus to 7.2° of valgus (*8*). Computer navigation has shown to reduce alignment outliers from 30% to 10% compared to conventional instrumentation (*13*). Unfortunately, navigation comes at a cost and it increases the average surgical time by about 20 minutes (*2*). Patient specific instruments (PSI) were introduced recently in knee arthroplasty to improve the accuracy of implantation, but also to reduce the surgical time and facilitate the workflow in the operating room (OR) (*1,19*).

The impact on modern orthopedic surgery of PSI and the potential cost for our society goes much further than the direct cost of guides and MRI. Patients and surgeons need to do new efforts and the time and effort spent at these activities have an economical cost (cost of effort and opportunity cost ; see Figure 1 for definitions). PSI as an innovation in knee arthroplasty can reach an economical break-even point by two pathways. Either by a substantial reduction of surgical time and the possibility to add an extra case to the operating list or by a reduction of alignment outliers and subsequently less failures of TKA, with a reduced cost of revision in the future (*16,20*).

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A recent paper showed that a substantial reduction in revision rate is necessary to support the additional costs of PSI, which was calculated previously as the cost of guides and MRI, therefore only representing a direct cost (see Figure 1 for definition) analysis for PSI estimated at 2500 USD (*26*). The authors mentioned in the limitations of their study that indirect costs (see Figure 1 for definition) were not calculated and should be added to the equation. Therefore this retrospective study was set up together with our Business school to estimate the indirect costs of PSI.

The hypotheses of this study were that (1) the total economical cost of PSI-assisted knee arthroplasty is much higher than the price of the guides and MRI (2) economically, the combined direct and indirect costs of PSI cannot currently justify an expanded use of this technology when looking at operating time or coronal alignment results.

MATERIALS AND METHODS

Demographics

The PSI group consisted of 41 patients (30 women/11 men) randomly selected for PSI surgery in 2009 with a mean (SD) age of 64.5 (10) and a BMI of 29.5 (5.4) kg/m^2. They lived at a mean (SD) distance of 47 (46.5) kms from the hospital. The control group consisted of 40 patients (32 women/8 men) with a mean (SD) age of 68.7 (11) years (n.s.) and a BMI of 30.8 (7.8) kg/m^2 (n.s.) who lived at a mean distance of 31.6 (39) kms from the hospital (n.s.). There was a follow-up of minimum 2 years with a mean (SD) of 3 (1) years on both groups.

Surgical technique

All 81 patients underwent a minimally invasive medial approach with implantation of a cemented posterostabilized (PS) Vanguard prosthesis (Biomet, Warsaw, US). The PSI-assisted TKA were all performed with the help of Signature (Biomet, Warsaw, US) and the conventional TKA with intramedullary alignment on the femur and extramedullary alignment on the tibia. Rehabilitation and deep vein thrombosis protocol were identical for both groups.

During surgery the total surgical time from skin-to-skin and the total time of patient in room representing the total surgical time and set-up time were measured with the hospital software system for OR planning.

Radiological measurements

Standing full leg radiographs were performed before and one year after surgery. All radiographs were digital

Direct cost : amount of money (price/cost) that can be completely and directly attributed to the production of specific goods or services. Usually it can be traced accurately to a cost object with little effort (e.g. ; cost of guides, cost of MRI).

Indirect cost : amount of money (price/cost) that is not directly accountable to a cost object and is usually difficult to be attributed and needs effort to calculate it (e.g. transportation cost of a patient, time spent at MRI facility).

Variable cost : a periodic cost or expense that varies with production output/volume or in surgery the amount of cases performed (e.g. gowns, gloves).

Fixed cost : a periodic cost that remains more or less unchanged irrespective of the output (e.g. exploitation cost of an OR).

Total cost : the total economic cost of production and can be the addition of direct and indirect cost or the addition of fixed and variable costs.

Breakeven point : point in time when forecasted revenue/value creation exactly equals the estimated total costs.

Cost of effort : the economical cost of the portion of time spent on a particular activity.

Opportunity cost : a benefit or value that must be given up to acquire or achieve something else.

Capital expenditure (CAPEX) : amount spent (price/cost) to acquire or upgrade productive assets in order to increase the capacity or efficiency of a company for more than one accounting period (e.g. ; instrumentation to perform TKA).

Value chain : value-adding activities that convert inputs into outputs which in turn add to the bottom line and help create competitive advantage.

Supply Chain : network or system of organizations, people and activities involved in moving a product from supplier to customer (e.g. PSI guides from producer to surgeon).

Fig. 1. — Economical definitions

and measurements were performed, using the PAC System, by one author (FP) performing each measurement twice and blinded for the study groups. The HKA-angle was measured according to Moreland *et al* (*14*) with varus being values lower than 180° and valgus values higher than 180°. Preoperative and postoperative values were obtained. No other radiological measurements were performed for this study.

Indirect Cost Allocation

In cost accounting several terms will be used like direct and indirect cost leading to total cost. Variable and fixed cost and opportunity cost and cost of effort. For the ease of understanding the definitions of these costs are resumed in Figure 1.

The indirect costs for performing a PSI-assisted knee arthroplasty are listed here and the method of cost calculation is explained :

Indirect Cost Analysis of performing PSI

1. Cost of Performing an MRI (not standard of care for TKA planning)

Direct cost of the travel to MRI facility : distance from their own home to the MRI facility and back was calculated for each patient with an internet based navigation program (www.mappy.be ; shortest distance settings) and this distance was multiplied with the average reimbursement rate per km for Belgium.

Direct cost of parking at MRI facility : the parking ticket was recuperated from patients coming for a PSI MRI and the direct cost calculated.

Opportunity cost for patient not working : the time the patient spend to perform the MRI, from leaving his house to returning to his home was calculated as an opportunity cost, since he was not able to engage into any other activity during that time, and this time was multiplied with the hourly rate of the patients job or economical value of time for people not working.

Economical impact of patient not working on Gross Domestic Product (GDP) : the same time as for previous point was calculated for the working people and multiplied by the mean hourly rate of contribution to the GDP.

Opportunity cost of administrative worker to introduce case in online system : time measured for administrative person to introduce patient in the online management system and create case. This average time was multiplied with the hourly wage rate of the administrative person.

Cost of effort/opportunity cost of MRI technologist performing MRI : time spent by the MRI technologist to perform an MRI that was not performed for diagnostic reasons and thus considered an opportunity cost. The time spent to perform the exam was multiplied by the hourly wage rate for the technologist.

Cost of effort/opportunity cost of downloading MRI to PSI online management system : average time spent by the technologist to open case online and download images to the online management system.

Cost of effort/opportunity cost of radiologist for protocol : time spent by the radiologist to look at MRI images (primarily to avoid a misdiagnosed cancer about the knee) and to edit a protocol needed for reimbursement of the MRI in Belgium.

2. Cost of PSI planning

Emails concerning the case introduction/validation dead line : time spent by the surgeon on each email that he receives by the online management system about each step of the process. This time spent was calculated and multiplied by the hourly rate of a surgeon.

Emails concerning the quality of MRI/refusals/administrative problems : time spent by the surgeon to solve issues with MRI like check quality of images, contacting patient for new scan, reschedule new appointment at shorter delay with radiologist, reschedule surgery was calculated and multiplied with the hourly rate of a surgeon.

Surgeons check of preoperative planning and validate the planning : mean time spent by surgeon to look at medical file of patient to check flexion/extension deficits or ligamentous laxity before planning. Opening the online management system, check surgical planning and validate planning. The time spent in the operating room to recheck the planning before the case starts. A fixed time of 5 minutes, considered representative for conventional surgical planning was deducted from this timing. The total time was multiplied by the hourly rate of the surgeon.

3. Cost of PSI supply chain management

Transportation of PSI guides to hospital : Zimmer Biomet Europe provided us the average prices for all PSI guides send around the world with their courier service (high volume favorable rate) what allowed us to calculate the average transportation price for PSI guides worldwide.

Reception of PSI guides by OR staff and delivery to sterilization department : time spent by the administrative personnel to reception the PSI guides and deliver them at sterilization department. Time spent was multiplied by the hourly wage rate of that member of staff.

Sterilization of PSI guides : total cost of sterilization in-house per item for PSI guides size is known and on-file in hospital. Price for sterilization and packaging of two PSI guides was delivered to us by senior management of in-house sterilization department.

Preparation of sterile PSI guides for right patient at right date : time spent by nurses to pick up PSI guides at sterilization department and to prepare it for the next day case. Time was multiplied by hourly wage rate for nurse.

4. Cost of PSI during surgery

Cost of surgical time : Fixed cost of one day of surgery overhead included (on-file hospital) divided by the resource hours (8 hours) allows to calculate fixed cost of surgical time per minute. To this fixed cost, the variable cost of performing TKA was added, leading to a total cost per minute to perform TKA in one operating room of our institution. Total surgical time and total time in operating room was calculated by software system of the anesthetists and direct timing by research nurse.

Reduction of instrument trays : total sterilization cost per tray (size, weight and amount of instruments variable) is known in our institution (on-file hospital). The amount of trays used were counted for PSI and conventional TKA.

Costs of hospital stay and follow-up

Difference in hospital stay with conventional surgery : length of stay for PSI compared to conventional group in days.

Difference in number of radiographs with conventional surgery : total amount of radiographs performed for follow-up of patient and compared between PSI and conventional group.

Difference in stay at home without working (in days) : total time in days before return to full time work was calculated for active workers and compared in between PSI and conventional group.

Statistical Analysis

Based on previous literature where the sample size for coronal alignment was estimated at 36 knees per group to have sufficient power (p = 0.80) to detect a significant difference (alpha = 0.05) *(5,34)* two groups of more than 36 patients were created in case some loss of follow-up or absent data would occur during the study. Sample characteristics are presented as numbers, means, and standard deviations. Statistical analysis was performed with Mann-Whitney *U* test for independent samples and the Student *t* test for dependent samples. All differences were considered significant at a probability level of 95% (P < 0.05). Analyses were performed using SPSS (Chicago, US) version 16.

Source of Funding

No external funding was used in support of this study.

RESULTS

The indirect cost allocation of performing an MRI is given in Table I and results in a total cost of 441.5€. The cost of the PSI planning is given in Table II and results in a total cost of 107€. The cost of PSI supply chain management is given in Table III and results in a total cost of 85€. The cost of PSI during surgery or the cost reduction is given in Table IV and results in a total cost reduction of 170€. The cost of hospital stay and follow-up or its reduction of costs is given in Table V and results in a total cost reduction of 0€. The indirect cost of PSI in Belgium can be estimated at 459€. The direct cost of the MRI is 183€ and of the guides 500€. This makes a total PSI cost of 1142€ for Belgian patients. The indirect cost makes up 40% of the total cost of PSI.

Total surgical time for conventional surgery was 87 (10) minutes and for the PSI group was 89 (11) minutes (n.s.). The total time in the operating room was 107 (12) minutes for conventional and 102 (10) minutes for the PSI group (n.s.). Instrument trays were reduced from 10 to 5 for the PSI cases (P < 0.05).

The mean (SD) hospital stay for the conventional group was 6.5 (1.4) days and for the PSI group 6.3 (1.8) days (n.s.). There were a mean (SD) of 16 (2) postoperative radiographs for both groups. The mean preoperative alignment for the conventional group was 176° (8°) and their postoperative alignment was 179.5° (2°). The mean preoperative alignment for the PSI group was 174° (6.5°) (n.s.) and their postoperative alignment was 179° (4°) (n.s.). The length of stay home without working was the same for both groups with a mean (SD) of 70 (20) days. No transfusions were necessary in either group.

Table I. — Cost of performing MRI

Cost allocation	Cost of performing MRI
Rescan cost MRI bad quality (2.5% of MRI)	4.5€
Travel to MRI facility	32.5€
Parking at MRI facility	4€
Opportunity cost of not working during MRI (3H)	120€
Impact on real GDP per hour worked (3H)	140€
Introduction of case by secretary in online system	15€
MRI technologist costs	34.5€
MRI technologist downloading images	34.5€
MRI protocol time by radiologist	56.5€
Total Cost	**441.5 €**

Table II. — Cost of PSI planning

Cost allocation	Cost of PSI planning
Emails to surgeon / time spend 5 min	21€
Emails to radiologist / time spend 5 min	21€
Validate PSI planning / time spend 15 min	65€
Total Cost	**107€**

Table III. — Cost of Supply chain management of PSI

Cost allocation	Cost of supply chain PSI guides
Transportation guides to hospital	70€
Reception of PSI guides OR / time spend 15 min	5€
Sterilization cost of PSI guides	4€
Preparation PSI guides matched with patient / 10 min	6€
Total Cost	**85€**

DISCUSSION

The most important finding of the present study was that the indirect cost of PSI makes up 40% of the total cost and is therefore important as a cost measure. The calculation of these costs should be included in any economical model that aims at estimating cost-effectiveness of this new technology.

Custom made cutting blocks can be cost-effective if there is no additional cost to patients and society or if they are able to reimburse their additional costs by improvements in surgical efficiency or better outcomes. This study calculated the indirect cost of PSI to have a realistic idea about the total cost of this technology. The total cost can give a better estimation of how much the surgical time should be reduced or the alignment outliers eliminated to add value to the surgical process.

A reduction of total operating room time per case can be obtained either by facilitating the surgical workflow (less surgical steps, less surgical time, definitive components ready before case) or by reducing the set-up times (less trays to open, less instruments to prepare, preoperative sizes of femur and tibia known). This could be economically rewarding if enough surgical time is found to allow an extra case to be performed during the same resource hours. Most of the PSI related studies showed a small reduction in tourniquet times of 5 to 10 minutes (*19,22,27*) and some showed a slight

Table IV. — Cost of PSI during surgery

Cost allocation	Cost of PSI during surgery
Surgery time / 2 min longer	13.5€
Set up time / 5 min shorter	(33.5)€
Reduction of instrument trays / 10 to 5	(150)€
Total Cost	**170€ cost reduction**

( ) € means in accounting terms a negative value or cost reduction in this case.

Table V. — Reduction in costs during hospital stay

Cost Allocation	Cost reduction during hospital stay
Difference in length of stay vs conventional	No difference
Difference in blood transfusion vs conventional	No difference
Less X-rays during follow-up vs conventional	No difference
Difference in alignment vs conventional	No difference
Difference in stay at home without working	No difference

improvement in total operating room time management with a reduction in set up time of around 10 minutes (*17,19,22*). A reduction in surgical time was not observed in this retrospective study but the possible causes for this were not analyzed. Other authors found the same because of frequent surgeon-directed changes during PSI-assisted TKA (*10,28*).

This paper calculated the indirect cost of PSI based on opportunity costs and cost of effort which should both go into the equation of cost-effectiveness. Times spent during non-surgical resource hours by the surgeon and the entire new organizational needs should be accounted for in a cost accounting model of PSI. Including the indirect costs of PSI, that make up 40% of the total cost, makes it easy to understand that the increase in variable cost per TKA by the use of PSI, will probably never reduce the surgical time enough to arrive at a financial break-even point based only on the reduction of OR time.

Another way of making PSI cost-effective would be by reducing the alignment outliers such that long-term survival of implants is guaranteed and therefore the economical cost of revision reduced for society (*26*). For the coronal plane a higher failure rate was observed if components were misaligned outside the window of 2.4° of varus to 7.2° of valgus (*8*). In another paper an eleven-fold increase in revision rates at fifteen years was observed with coronal misalignment (54% compared with 4.7%) (*18*). However these classic concepts of alignment have been challenged by recent literature making the range of acceptable outliers wider then previously presumed (*3,21*). In an economic model these last papers allow of course for more outliers and thus for the choice of conventional instruments. Moreover Nam *et al* recently observed the same rate of outliers (30%) in the frontal plane with PSI as with conventional instrumentation (*15*).

For the sagittal plane unfortunately there are no papers about its importance on survival of implants or the effect on functional results. Moreover recent navigation controlled studies showed that the results for PSI were less accurate in the sagittal plane (*6,12,31,33*).

For the axial plane one paper showed more accuracy for one PSI system compared to the conventional results of one surgeon (*9*). Lustig *et al* did not confirm this finding for the same PSI system during a navigation controlled study (*12*). And in a recent paper Roh *et al* found no advantage for a CT-based PSI system compared to conventional surgery (*23*). More results are necessary and especially studies on the impact of function and pain for better rotationally aligned knees.

Despite that it was not the aim of this study a final parameter to take into account in an economic model on cost-effectiveness of instruments that increase the accuracy of knee implantation would be the age of the patient at the time of the surgery (*4*). Patients undergoing knee arthroplasty should be stratified by age and presence of coexisting conditions (co-morbidity) to estimate the proportion of patients that would remain alive with their original implant because of improved alignment at older age (*29*).

When the reduction of alignment outliers with PSI is discussed a comparison to cost-effectiveness in navigation can be made. Dong *et al* analyzed the cost-effectiveness of computer-navigation and concluded it was a cost-saving technology in the long term and may offer small additional QALY's (*7*). Novak *et al* calculated that computer-navigation was cost effective if the added cost was 629 US Dollar or less per operation (*18*). Kusuma *et al* used a Taguchi loss function for varus/valgus alignment, expressed as $L(y) = \$326.80\ y^2$ where y was the deviation from ideal varus/valgus angle. A difference of 2304$ in favor of computer navigation was observed (*11*). Slover *et al* showed that in high volume centers achieving cost effectiveness by reduction in revision rates by using navigation was even more important (*25*). Looking at these navigation papers it was understood that the total cost of PSI was substantial higher and therefore asks for alignment results that are superior to the ones published for navigation.

Some other authors analyzed the cost-effectiveness of PSI too. Tibesku *et al* analyzed the cost-effectiveness of PMI (Visionaire, Smith&Nephew, Memphis, US) but calculated only a direct cost for the guides (700€) and a minimal imaging cost of 82€ that they compared to cost savings in time and sterilization cost. They found a difference of only 59€ in favor of the conventional instrumentation and argumented that an extra case a day would make the difference in favor of PSI (*32*). Recently Watters *et al* compared the cost of PSI with conventional and navigated TKA. They observed a slight cost advantage of 270 USD for PSI compared to navigation, explained by longer operating times for computer navigation and lower sterilization costs for PSI, but PSI was 533 USD more expensive than conventional TKA by the cost of the guides. The indirect cost of the PSI process nor the direct cost of the MRI was not included in their analysis (*35*). Barrack *et al* analyzed the cost of PSI too, based on operating times and instrument processing costs and concluded that it was not cost-effective with a total cost of +/- 1500 USD for PSI (*1,19*). Slover *et al* had a cost of 2500 USD at their institution resulting in a cost per QALY of 2900 to 4700 USD (*26*). They included a sensitivity analysis between cost and reduction in revision rate. Applying our total cost calculation formula to their findings gives a total cost of 3500 USD for PSI by analogy. At this amount, sensitivity analysis shows that PSI should reduce the revision rate by 60% compared to the revision rate after conventional TKA to be cost-effective. In this study the PSI group had no better mean mechanical alignment, if that could be a predictor for future revision, and a higher SD of 4° with maximal outliers of 173° and 189° HKA-angles. These patients are probably exposed to a risk of earlier failure rather than a reduction of their revision rate (*8*).

This study has several weaknesses. A first weakness is that we did not calculate the impact of the PSI-related MRI's on the general waiting list to obtain an MRI appointment for other people that need an MRI for their knee diagnostic problem and the impact of their time not working on the GDP.

A second weakness is that the costs in this study are based on a pinning system and that cutting systems reduce the surgical time probably more drastically and gain more money in OR time (*32*).

A third weakness is that most of the literature on PSI accuracy and the alignment results of this study are based only on frontal alignment and that PSI is supposed to increase accuracy in the three planes. If it does, its cost-effectiveness would be higher than if only the coronal plane is evaluated. Heyse *et al* found less rotational outliers in the PSI group (2.2%) compared to the conventional group (22.9%) (*9*) but this was not confirmed by other authors on the same PSI system with only 77% within 3° of the surgical epicondylar axis (*12*).

A final weakness is that the individual items in the cost allocation were calculated on the macroeconomic data of Belgium or Europe where the study took place. Individual variation within countries exists and especially the extension to the US cost was arbitrarily by using a formula of 40%

indirect cost added to a previously published direct costs of 2500 US Dollar (*26,28*). However the detailed tables are available and if wanted an itemized calculation can be performed by each surgeon in each individual country.

The strength of this study lies probably in the fact that it was organized by an orthopedic surgeon with an MBA in collaboration with an economics professor of the Business School (Louvain School of Management) where both teach. It was proven that the total cost of PSI because of indirect costs is much higher than the direct cost estimations used in the past. Furthermore looking at operating times and coronal alignment results no value was found in the use of PSI.

The financial breakeven point for PSI when looking at total cost for this innovation will need an effort from our commercial partners. Substantial reductions of capital expenditure (CAPEX) can be obtained by orthopaedic companies if PSI is combined with disposable instruments and just-in-time delivery of implants. The reduction of inventory in the hospitals, the loss of components with small or big sizes at expiration date and the money invested in conventional instrument trays could change the value chain of orthopaedics as we know it today. The working capital freed up by this innovation should be shared with the hospitals and society and not only lead to increase of shareholders wealth (*30*). An equation between the reduction of fixed (OR time) and variable (trays) costs for the hospital, the reduction of future costs of revision, if alignment outliers can be avoided, for our society and the reduction of capital expenditures for the companies should lead to a cost share agreement to cover the total cost of PSI if stakeholders would decide it is of future value.

CONCLUSIONS

The value of PSI guides will depend on the surgical precision it can deliver in the three planes of the knee. Whenever the same accuracy can be obtained in the frontal plane as with computer-navigation, a cost price up to 1708 euro can be breakeven. However the strength of PSI should lie in improved accuracy in the three planes and as a bonus in a reduction of surgical time and set up times what was never obtained with navigation. Looking at the combined direct and indirect cost of PSI, with a total cost of 1142 euro, a cost-share program with the industry seems necessary for this innovation

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