

Patient specific instrumentation: A minimally invasive technique for knee arthroplasty

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Abstract

Patient specific instrumentation (PSI) is considered a minimally invasive technique regardless of whether the skin incision is small or traditionally long. PSI provides two pieces of instruments to replace the complex conventional instruments that may reach up to 100 pieces. PSI eliminates the need for using the invasive intramedullary rods that perforate the medullary canal leading to higher risk of bleeding, fat embolism, infection and fractures. PSI also reduces operative time and speeds the recovery of patients. In this review, the authors collect the data given on total knee arthroplasty (TKA) using PSI. The criteria for TKA as well as the development of different surgical techniques and how PSI would benefit the surgeons and patients to conduct a successful surgery have been discussed. (El Med J 2:4; 2014)

Keywords: Patient Specific Instrumentation, Total Knee Arthroplasty, Minimally Invasive

Introduction

Total knee arthroplasty (TKA) is an effective method in the treatment of severe osteoarthritis of the knee joint. TKA aims to restore neutral limb alignment and establish adequate soft tissue balance. Malalignment may lead to pain, stiffness, instability, wear, osteolysis and increased risk of loosening. The aim of the surgery is to make proximal tibial and distal femoral bone cuts at 90 degrees to their respective mechanical axis [1].

TKA is considered one of the most successful orthopedic procedures, and since its introduction in 1960, much effort has been paid for improving the designing of the implants, standardization of surgical techniques, fixation methods, and infection prevention measures [2, 3]. Survival rate after TKA for old age group (>60 years old) has been determined to be as high as 85-95% in 10-20 years, as opposed to young, active and obese patients as well as cases difficult for revision [4-14].

Computer-assisted orthopedic surgery (CAOS) is an enabling technology that has the ability to improve accuracy and reproducibility of TKA surgical techniques. CAOS aims to provide the best option for TKA based on perfect preoperative picture which accurately shows the position of the center of the joint in order to provide even alignment and perfect level of bone cuts. It also aims at avoiding intramedullary perforation and solving the problem of in-between sizes. CAOS thus decreases the number of instruments and, in turn, the cost effectiveness and operative time [15]. Moreover, with computer assistance, even unexperienced surgeons are able to get better alignment immediately and constantly [16]. Improved alignment has led to better survival rates and clinical results. Merloz et al found that nearly 40-50% of revision knees could be prevented if perfect alignment and perfect ligament balancing is ensured [17].

Criteria for TKA

In TKA, the location and angle of insertion of femoral intramedullary rod are very important and account for coronal and sagittal orientation of femoral component [18-20]. Minor changes in location of entry point of intramedullary rod increase the chances of malalignment and put the knee in the category of "outlier". The intramedullary rod

can lead to malalignment if its insertion angle and its position in canal are not accurate [21-23]. Opening the medullary canal also predisposes the surgical subject to more bleeding, more chances of infection and embolism and chance of fracture [24-26]. The rotational orientation of femoral component can be determined by the palpable axes within the knee joint (mainly epicondylar and posterior condylar axes). The transepicondylar axis is less predictable and significantly more externally rotated than the anteroposterior axis [23, 27, 28]. The femoral component sizing is not fully proven [29]. The stylus of the anterior referencing systems has the limitations that it may lead to posterior placement of stylus or possible undersizing [27]. A study by Parratte et al concluded that postoperative mechanical axis does not affect the 15-year survivorship of implants [30].

Another problem that may risk notching or decrease the space between the posterior coronal cut on the distal femur and the transverse cut on proximal tibia (flexion gap) is the "in-between sizes." Navigated TKA can oversize femur. In the conventional instrumentation system, the femoral sagittal cut angulation is determined by the position of intramedullary rod being in certain degrees of flexion to mechanical axis. In navigated TKA, this cut is at 90 degrees to the mechanical axis (placing the femoral component in extension) in comparison to conventional technique. The femur gets oversized because of this relative extension and to prevent notching (particularly in curved femurs). The inner surface of the anterior part of femoral implant should lie flushed with the anterior cortex, replicating the patient's anatomy [27, 31].

Surgical factors are very important for the long-term durability of implants [32-35]. The tendency to leave the knee in slight flexion or to put femoral component in internal rotation has been noticed. Minor errors in bone cuts cannot be visualized in conventional technique [36]. The fiddle factor, the assembly, disassembly and sterilization of several tools might affect the accuracy of bone cuts and put the patient under the risk of contamination [37].

Patient specific instrumentation

Patient specific instrumentation (PSI) is a new concept that develops different aspects of computer assisted technologies to perform vir-

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tual surgery and produce patient specific instruments based on pre-operative imaging. It does not have the drawbacks of navigation and robotics, such as high cost and complexity.

Cost, operative time, alignment and number of outliers are all questionable; they might vary according to each orthopedic teamwork results. Cost is a perceived barrier to using the custom-fit positioning technique, and Mont et al have found that surgeons who use this technique have reduced procedure time [38]. A prospective, randomized trial by Hamilton et al has shown that PSI did not shorten surgical time or improve alignment, compared with the conventional technique, but reduced the required number of trays [39].

In addition to the time of the theatre (that has economic implications too), the navigation systems are costly, need training and have a learning curve. Experienced surgeons complain of not getting the "feel of the knee" [40]. In terms of the cost factor, a few surgeons have suggested to utilize navigation-system-equipped orthopedic hospitals as referral hospitals, where complicated cases can be referred [41, 42]. PSI exploits the accuracy of computer and matches the patient's anatomy. It decreases the surgical time and soft tissue dissection (which makes simultaneous bilateral TKA safer) and is proven affordable too [43].

In an experimental study by Hafez et al, a number of 45 TKA (29 plastic and 16 cadaveric knees) were performed using PSI without

conventional instrumentations, intramedullary perforation, tracking nor registration [44]. The study revealed mean errors for alignment and bone resection within 1.7° and 0.8 mm (maximum, 2.3° and 1.2 mm, respectively) [1].

PSI requires a CT scan or MRI of the patient's knee (in addition to the routine X-rays). Ensini et al treated 25 patients with a CT-based PSI system and other 25 patients with an MRI/X-ray-based system, and both PSI systems showed good alignment in the coronal plane in all stages. However, for a few measurements, a better performance was observed in the MRI/X-ray-based system than in the CT-based system [45]. However, MRI has been shown to provide a suboptimal accuracy and inferior quality 3D image of the knee. White et al have found that the 3D bone models generated from MRI were dimensionally less accurate and visibly inferior in comparison to CT-based 3D models [46]. The external surfaces of MRI models were rough because of soft tissue structures which could not be removed by the threshold. The technique of segmentation (removal of soft tissues) of an MRI data is difficult, time consuming, subjective and imperfect. In fact, many research works have focused on improving segmentation of MRI-based data [47].

The preoperative planning for a technique of PSI for TKA includes sizing, alignment and bone cutting based on imaging and then designing and producing femoral and tibial templates that act as cutting blocks (Figure 1).

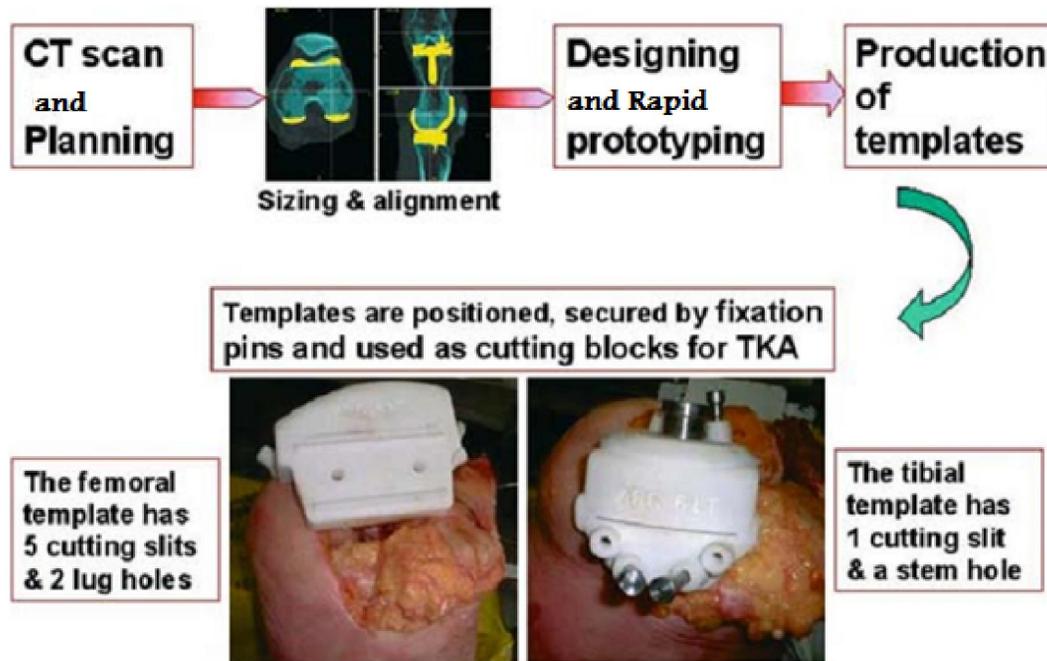


Figure 1: Patient specific instrumentation technique.

Majority of the conventional jigs (navigation system is also based on these jigs) is based on the Caucasian anatomy. Fitting a different-size implant to an individual requires either cutting the implant, bone or soft tissue, which increases the role of surgeon in pain management and infection control [48]. The main idea of PSI is that knee-joint arthroplasty procedures can be individualized, with benefits including precise realignment of the normal mechanical axis of the operated

lower limb, minimized resection of the patient's bony tissue, reduced surgical time, simplified instrumentation, reduced perioperative and postoperative blood loss, no need of femoral medullary cavity reaming and reduced rate of thromboembolic complications.

The custom-fit TKA is designed to recreate the natural prearthritic alignment of the patient's knee with the goal of increasing function.

Individuals who undergo custom-fit placement show better stability and postoperative mechanical axis alignment and also possess acceptable clinical outcome at three months. The consistent sizing of the implants, secure fit of the femoral and tibial guides, short operative duration, low transfusion rate and lack of fat emboli support continued use of the custom-fit technique [49-51].

Walker et al found that while newer technologies can offer further improvement in total knee systems, implementation will be strongly affected by the need to satisfy the competing requirements [52]. However, Boonen et al compared patient specific to intramedullary-aligned TKA and found that the fraction of outliers for patient specific TKA was relatively higher, although it has proven better accuracy, lower blood loss rate and shorter operating time [53].

Roh et al assessed the precision and reliability of patient specific TKA in comparison with the conventional technique. They concluded that the accuracy was comparable between 2 patients' groups (outliers in hip-knee-ankle angle was 12% in the PSI group and 10% in the conventional instrument group) whereas sagittal alignment and femoral component rotation did not differ in terms of outliers. Moreover, they reported that the PSI procedures have been aborted frequently, incurring expenses that did not benefit patients [54].

Another comparison between the conventional and patient specific TKA procedures shows that PSI technology is superior to conventional instrumentation in achieving a neutral mechanical axis following TKA, but it needs further follow-up to ascertain the long-term impact of these findings [55]. PSI allows the optimum balance of technology and conventional surgery by reducing the complexity of conventional alignment and sizing tools. Thus, the advantages of accuracy and precision claimed by computer navigation techniques are achieved without the disadvantages of additional intraoperative inventory, new skills, or surgical time [56].

Although this technique could be used for routine primary knee, another study has shown the clinical application for a few absolute indications of PSI (e.g., old malunited distal femur supracondylar osteotomies, ASA grade 3-4 patients where time of surgery is important and hemophilic arthropathy where intramedullary jigs have to be avoided and surgery time has to be decreased) [44].

PSI system enables less number of instrumentations and less stress during surgery. It can benefit the hospital by improving operating room time efficiencies by shorter setup time and eliminating the cleaning, sterilization and inventory costs [57]. It will definitely improve ergonomics at work place and might prevent burn-out of the orthopedic surgeons (as it relieves the clinician from multiple intraoperative decisions), particularly when a recent economic model has predicted a supply side crisis [58-60].

PSI has an additional benefit on surgical teaching. Trainees can learn preoperative planning on software and order the manufacturer to make a virtual bone model. Simulation can play an important role for the training surgeons [61]. The surgeons can use PSI as pin locators and can check the intraoperative accuracy of these locators before making the bone cuts.

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References

- Hafez MA, Chelule KL, Seedhom BB, Sherman KP. Computer-assisted total knee arthroplasty using patient-specific templating. *Clin Orthop Relat Res.* 2006 Mar;444:184-92.
- Chapman's Orthopaedic Surgery, 3rd Edition CHAPTER 108- PRIMARY TOTAL KNEE ARTHROPLASTY ; Dennis W. Burke, Hugh O'Flynn P. 2869
- Gunston FH. Polycentric knee arthroplasty. Prosthetic simulation of normal knee movement. *J Bone Joint Surg Br.* 1971 May;53(2):272-7.
- Rasquinha VJ, Ranawat CS, Cervieri CL, Rodriguez JA. The press-fit condylar modular total knee system with a posterior cruciate-substituting design. A concise follow-up of a previous report *J Bone Joint Surg Am.* 2006 May;88(5):1006-10.
- Vessely MB, Whaley AL, Harmsen WS, Schleck CD, Berry DJ. The Chitranjan Ranawat Award: Long-term survivorship and failure modes of 1000 cemented condylar total knee arthroplasties *Clin Orthop Relat Res.* 2006 Nov;452:28-34
- Parsch D, Krüger M, Moser MT, Geiger F. Follow-up of 11-16 years after modular fixed-bearing TKA. *Int Orthop.* 2009 Apr;33(2):431-5
- E. Rinonapoli, G. B. Mancini, A. Azzara, P. Aglietti Long-term results and survivorship analysis of 89 total condylar knee prostheses *The Journal of Arthroplasty, Volume 7, Issue 3, September 1992, Pages 241-246*
- Attar FG, Khaw FM, Kirk LM, Gregg PJ. Survivorship analysis at 15 years of cemented press-fit condylar total knee arthroplasty *J Arthroplasty.* 2008 Apr;23(3):344-9
- Tayot O, Ait Si Selmi T, Neyret P. Results at 11.5 years of a series of 376 posterior stabilized HLS1 total knee replacements. Survivorship analysis and risk factors for failure. *Knee.* 2001 Oct;8(3):195-205
- Pradhan NR, Gambhir A, Porter ML. Survivorship analysis of 3234 primary knee arthroplasties implanted over a 26-year period: a study of eight different implant designs *Knee.* 2006 Jan;13(1):7-11
- Abdeen AR, Collen SB, Vince KG. Fifteen-year to 19-year follow-up of the Insall-Burstein-1 total knee arthroplasty *J Arthroplasty.* 2010 Feb;25(2):173-8
- Ritter MA, Wing JT, Berend ME, Davis KE, Meding JB. The clinical effect of gender on outcome of total knee arthroplasty. *J Arthroplasty.* 2008 Apr;23(3):331-6.
- Ritter MA, Berend ME, Meding JB, Keating EM, Faris PM, Crites BM. Long-term followup of anatomic graduated components posterior cruciate-retaining total knee replacement. *Clin Orthop Relat Res.* 2001 Jul;(388):51-7
- Sierra RJ, Cooney WP 4th, Pagnano MW, Trousdale RT, Rand JA. Reoperations after 3200 revision TKAs: rates, etiology and lessons learned. *Clin Orthop Relat Res.* 2004 Aug;(425):200-6.
- Klein GR, Austin MS, Smith EB, Hozack WJ. Total knee arthroplasty using computer-assisted navigation in patients with deformities of the femur and tibia. *J Arthroplasty.* 2006 Feb;21(2):284-8.
- Carter RE 3rd, Rush PF, Smid JA, Smith WL. Experience with computer-assisted navigation for total knee arthroplasty in a community setting. *J Arthroplasty.* 2008 Aug;23(5):707-13
- Merloz P, Tonetti J, Pittet L, Coulomb M, Lavalée S, Sautot P. Pedicle screw placement using image guided techniques. *Clin Orthop Relat Res.* 1998 Sep;(354):39-48.
- Laskin RS. Instrumentation pitfalls: you just can't go on autopilot! *J Arthroplasty.* 2003 Apr;18(3 Suppl 1):18-22.
- Jeffery RS, Morris RW, Denham RA. Coronal alignment after total knee replacement. *J Bone Joint Surg Br.* 1991 Sep;73(5):709-14.
- Mihalko WM, Boyle J, Clark LD, Krackow KA. The variability of intramedullary alignment of the femoral component during total knee arthroplasty. *J Arthroplasty.* 2005 Jan;20(1):25-8.
- Fehring TK, Odum SM, Troyer JL, Iorio R, Kurtz SM, Lau EC. Joint replacement access in 2016 a supply side crisis *J Arthroplasty.* 2010 Dec;25(8):1175-81
- Mahaluxmivala J, Bankes MJ, Nicolai P, Aldam CH, Allen PW. The effect of surgeon experience on component positioning in 673 Press Fit Condylar posterior cruciate-sacrificing total knee arthroplasties. *J Arthroplasty.* 2001 Aug;16(5):635-40.
- J Arthroplasty.* 2001 Apr;16(3):301-5. Determining femoral rotational alignment in total knee arthroplasty: reliability of techniques. Katz MA, Beck TD, Silber JS, Seldes RM, Lotke PA.

24. Kim YH. Incidence of fat embolism syndrome after cemented or cementless bilateral simultaneous and unilateral total knee arthroplasty. *J Arthroplasty*. 2001 Sep;16(6):730-9.
25. Beldame J, Boisrenoult P, Beauflis P. Pin track induced fractures around computer-assisted TKA. *Orthop Traumatol Surg Res*. 2010 May;96(3):249-55.
26. Jung HJ, Jung YB, Song KS, Park SJ, Lee JS. Fractures associated with computer-navigated total knee arthroplasty. A report of two cases. *J Bone Joint Surg Am*. 2007 Oct;89(10):2280-4.
27. Jenny JY, Boeri C. Low reproducibility of the intra-operative measurement of the transepicondylar axis during total knee replacement. *Acta Orthop Scand*. 2004 Feb;75(1):74-7.
28. Bonnin MP, Saffarini M, Mercier PE, Laurent JR, Carrillon Y. Is the Anterior Tibial Tuberosity a Reliable Rotational Landmark for the Tibial Component in Total Knee Arthroplasty? *J Arthroplasty*. 2010 May 7
29. Incavo SJ, Coughlin KM, Beynonn BD. Femoral component sizing in total knee arthroplasty: size matched resection versus flexion space balancing. *J Arthroplasty*. 2004 Jun;19(4):493-7.
30. Parratte S, Pagnano MW, Trousdale RT, Berry DJ. Effect of postoperative mechanical axis alignment on the fifteen-year survival of modern, cemented total knee replacements. *J Bone Joint Surg Am*. 2010 Sep 15;92(12):2143-9. doi: 10.2106/JBJS.I.01398.
31. Chou WY, Ko JY, Wang CJ, Wang FS, Wu RW, Wong T. Navigation-assisted total knee arthroplasty for a knee with malunion of the distal femur. *J Arthroplasty*. 2008 Dec;23(8):1239.e13-9.
32. Naudie DD, Ammeen DJ, Eng G, Rorabeck CH. Wear and osteolysis around total knee arthroplasty. *J Am Acad Orthop Surg*. 2007 Jan;15(1):53-64.
33. Stulberg SD. How accurate is current TKR instrumentation? *Clin Orthop Relat Res*. 2003 Nov;416:177-84.
34. Kinzel V, Scaddan M, Bradley B, Shakespeare D. Varus/valgus alignment of the femur in total knee arthroplasty. Can accuracy be improved by pre-operative CT scanning? *Knee*. 2004 Jun;11(3):197-201
35. Sharkey PF, Hozack WJ, Rothman RH, Shastri S, Jacoby SM. Insall Award paper. Why are total knee arthroplasties failing today? *Clin Orthop Relat Res*. 2002 Nov;404:7-13
36. Yau WP, Leung A, Chiu KY, Tang WM, Ng TP. Intraobserver errors in obtaining visually selected anatomic landmarks during registration process in nonimage-based navigation-assisted total knee arthroplasty: a cadaveric experiment. *J Arthroplasty*. 2005 Aug;20(5):591-601.
37. The Department of Health. Risk assessment for transmission of vCJD via surgical instruments: a modelling approach and numericalscenarios. Available at: www.dh.gov.uk Accessed July 19, 2005.
38. Mont MA, Johnson AJ, Zywiell MG, Bonutti PM: Surgeon Perceptions Regarding Custom-fit Positioning Technology for Total Knee Arthroplasty. *Surg Technol Int*, 20:348-351.
39. Hamilton WG, Parks NL, Saxena A. Patient-specific instrumentation does not shorten surgical time: a prospective, randomized trial. *J Arthroplasty*. 2013 Sep;28(8 Suppl):96-100.
40. Callaghan JJ, Liu SS, Warth LC. Computer-assisted surgery: a wine before its time: in the affirmative. *J Arthroplasty*. 2006 Jun;21(4 Suppl 1):27-8.
41. Rosenberger RE, Hoser C, Quirbach S, Attal R, Hennerbichler A, Fink C. Improved accuracy of component alignment with the implementation of image-free navigation in total knee arthroplasty *Knee Surg Sports Traumatol Arthrosc*. 2008 Mar;16(3):249-57
42. Slover JD, Rubash HE, Malchau H, Bosco JA. Cost-Effectiveness Analysis of Custom Total Knee Cutting Blocks. *J Arthroplasty*. 2012 Feb;27(2):180-5. doi: 10.1016/j.arth.2011.04.023. Epub 2011 Jun 14
43. T Wu, F Portheine, A Popovic, P Bast, M Wehmoeller and K Rademacher International Congress Series Volume 1256, June 2003, Pages 703-709 CARS 2003. Computer Assisted Radiology and Surgery. Proceedings of the 17th International Congress and Exhibition.
44. Hafez MA. Patient specific instrumentation: The past, the present and the future. In *Improving Accuracy in knee Arthroplasty*. Edited by Thienpont, E., New Delhi, India, Jaypee Brothers Medical Publishers (P) Ltd. 2012, 149-168.
45. Ensini A, Timoncini A, Cenni F, Belvedere C, Fusai F, Leardini A, Giannini S. Intra- and post-operative accuracy assessments of two different patient-specific instrumentation systems for total knee replacement. *Knee Surg Sports Traumatol Arthrosc*. 2013 Sep 24. [Epub ahead of print]
46. White D, Chelule KL, Seedhom BB. Accuracy of MRI vs CT imaging with particular reference to patient specific templates for total knee replacement surgery. *Int J Med Robot*. 2008 Sep;4(3):224-31.
47. Baldwin MA, Langenderfer JE, Rullkoetter PJ, Laz PJ. Development of subject-specific and statistical shape models of the knee using an efficient segmentation and mesh-morphing approach. *Computer Methods Programs Biomed*. 2010 Mar;97(3):232-40.
48. Peersman G, Laskin R, Davis J, Peterson MG, Richart T. Prolonged operative time correlates with increased infection rate after total knee arthroplasty. *HSS J*. 2006 Feb;2(1):70-2.
49. Spencer BA, Mont MA, McGrath MS, Boyd B, Mitrick MF (2009) Initial experience with custom-fit total knee replacement: intra-operative events and long-leg coronal alignment: *Int Orthop*.: 33(6):1571-5.
50. Howell SM, Kuznik K, Hull ML, Siston RA (2008) Results of an initial experience with custom-fit positioning total knee arthroplasty in a series of 48 patients. *Orthopedics*: 31(9):857-63.
51. Slamin J, Parsley B. Evolution of customization design for total knee arthroplasty. *Curr Rev Musculoskelet Med*. 2012 Dec;5(4):290-5. doi: 10.1007/s12178-012-9141-z.
52. Walker PS, Yildirim G, Arno S, Heller Y. Future directions in knee replacement. *Proc Inst Mech Eng H*. 2010;224(3):393-414
53. Bert Boonen, Martijn G M Schotanus, and Nanne P Kort. Preliminary experience with the patient-specific templating total knee arthroplasty_40 cases compared with a matched control group. *Acta Orthop*. 2012 August; 83(4): 387-393.
54. Roh YW, Kim TW, Lee S, Seong SC, Lee MC. Is TKA Using Patient-Specific Instruments Comparable to Conventional TKA? A Randomized Controlled Study of One System. *Clin Orthop Relat Res*. 2013 Dec;471(12):3988-95.
55. Daniilidis K, Tibesku CO. A comparison of conventional and patient-specific instruments in total knee arthroplasty. *Int Orthop*. 2013 Jul 31. [Epub ahead of print]
56. Krishnan SP, Dawood A, Richards R, Henckel J, Hart AJ. A review of rapid prototyped surgical guides for patient-specific total knee replacement. *J Bone Joint Surg Br*. 2012 Nov;94(11):1457-61. doi: 10.1302/0301-620X.94B11.29350.
57. C. Lavernia, V.H. Hernández, J.P. Hommen Chapter 8 Cost Analysis of Navigation.
58. Stone R, McCloy R. Ergonomics in medicine and surgery *BMJ*. 2004 May 8;328(7448):1115-8.
59. Saleh KJ, Quick JC, Sime WE, Novicoff WM, Einhorn TA. Recognizing and preventing burnout among orthopaedic leaders. *Clin Orthop Relat Res*. 2009 Feb;467(2):558-65.
60. Garske T, Ward HJ, Clarke P, Will RG, Ghani AC. Factors determining the potential for onward transmission of variant Creutzfeldt-Jakob disease via surgical instruments. *J R Soc Interface*. 2006 Dec 22;3(11):757-66.
61. E. Pietka and J. Kawa (Eds.), Computer Enhanced Orthopedics Wojciech Glinkowski. Information Tech. in Biomedicine ASC 47, pp. 28-43, 2008.