## Original Article

# Techno-economical analysis of the potential rise of demand for the artificial high flexion knee in the Indian orthopaedics market

Received (in revised form): 4th April 2009

**Sudesh Sivarasu**
is working as an associate professor in the School of Bio Sciences & Technology, and heads the Biomedical Engineering Group of VIT University, India. He works in the area of biomedical engineering, rehabilitation engineering, biomechanics, health technology management and health-care management. He has many international publications and patents to his credit. He has presented lectures in various national and international conferences in his areas of interest.

**Sumiya Sivarasu**
is a postgraduate in business administration from Mangalore University and a research scholar from Dravidian university, Kuppam, Andra Pradesh; and a faculty in New College Institute of Management, Chennai. She has more than 8 years of experience in teaching postgraduate students. She has published more than 15 articles and research papers in marketing, human resource management and services marketing.

**S. Sheelarani**
is a postgraduate in business administration and computer applications, with a doctorate in the area of service quality from the University of Madras. She is currently a professor in New College institute of Management, Chennai. She has published more than 100 research papers and articles spanning over service quality management, marketing management and human resource management. She has been a consultant to several public and private organizations. She has more than 20 years of experience in teaching at various business schools.

**T. Lazar Mathew**
is currently the director of the School of Bio Sciences & Technology, VIT University, Vellore. He had a brilliant academic record of topping the University, both in graduate and postgraduate courses. He is a specialist in environmental physiology and medicine with a doctorate (PhD) from Delhi University in the subject. He was instrumental in establishing the High Altitude Medical Research Centre at Leh (12000 feet high). He is a fellow of the Academy of Biomedical Scientists (FABMS), a fellow of the International Medical Sciences Academy (FIMSA) and also a fellow of the Indian Medical Sciences Academy (FAMS).

**ABSTRACT The artificial knee is used in the bone resurfacing of the arthritis-affected knee using a procedure called Total Knee Arthroplasty or Total Knee Replacement. The article discusses the existing artificial knees that are in the Indian market and the market share analysis of different players in this market. The article also forecasts the expected sales of this orthopaedic implant until the year 2010. The article compares the international artificial knee implant technology scenario with that of the Indian market. The international artificial knee market is compared with the Indian knee implants market. The article concludes with the requirements of an ideal artificial knee that would suit not only the Indian market, but also the Eastern world.**

**Correspondence:**
Sudesh Sivarasu
Biomedical Engineering Division, School of Biosciences and Technology, VIT University, Tiruvalam Road, Vellore, Tamil Nadu 632014, India

*Journal of Medical Marketing* (2010) **10,** 115–121. doi:10.1057/jmm.2009.29; published online 19 February 2010

**Keywords:** Indian orthopaedic market; artificial knee; market share analysis; market estimate; total knee replacement

## INTRODUCTION – THE ARTIFICIAL KNEE MARKET

The artificial knee replacement has been in existence for more than six decades, during which time there have been many developments and advancements in terms of both the designs employed and the technologies applied in the design and manufacture of these important devices. Total Knee Arthroplasty (TKA) has become a routine part of any regular orthopaedic clinic. The majority of advanced knee implants manufactured using leading edge technologies are developed in the Western countries, especially the United States and the United Kingdom and the development of these technologies in developing markets remains an aspiration.

## THE ARTIFICIAL KNEE TECHNOLOGY SCENARIO

### The international technology scenario[1–10]

The market for artificial knees is heavily consolidated, the main manufacturers being Biomet, Depuy (a division of Johnson & Johnson), Wright Medical Group Inc., Zimmer Holdings Inc., Stryker Corporation and Smith & Nephew.

For instance, Wright Medical Group maintains a comprehensive quality system that is certified to the European standards ISO 9001 and ISO 13485 and to the Canadian Medical Devices Assessment System. It is accredited by the American Association of Tissue Banks and has registrations with the US Food and Drug Administration (FDA) as both a medical device establishment and as a tissue establishment. These certifications and registrations require periodic audits and inspections by various regulatory entities to determine if the company has systems in place to ensure the product is safe and effective for its intended use and that the company is in compliance with applicable regulatory requirements. The quality system exists so that management has the proper oversight, designs are evaluated and tested, production processes are established and maintained, and monitoring activities are in place to ensure products are safe, effective and manufactured according to our specifications. Consequently, the quality system provides the way for the company to ensure they design and build quality into their products while meeting global requirements.

Johnson & Johnson's DePuy Orthopaedics manufactures more than 200 products, including well-known offerings such as *Sigma*® Knees, which offer a wide range of sizes, shapes and materials so that surgeons can select the knee replacement that is right for the patient's lifestyle. *Pinnacle*® Hip Solutions with TrueGlide™ technology help provide a smoother range of natural hip motion.[11]

### The Indian technology scenario[12–14]

Knee replacement has been carried out in India for more than 20 years. Indian surgeons have pioneered the surgical aspects of the TKA and this is evidenced by the increase in the post-surgical Quality of Life (QoL). Leaving out the Western countries, India is one of the few nations that use cutting edge technologies in this area of surgery. However, of the implants used in TKA, 95 per cent are imported from the leading orthopaedic medical devices companies in the west. Most of the instruments that are used for the surgery are also imported.

In India, there are no FDA-approved medical device manufacturing centres specifically in the field of orthopaedic joint implants. There are very few companies that manufacture artificial knee joints in India. INOR is one such company and manufactures only one model of artificial knee that comes in four

  

different sizes. The artificial knee is made out of Cobalt Chromium alloy and Ultra High Molecular Weight Polyethylene.

Another Indian example is Invicta, a Chennai based company that had a licence agreement with Endotech and then improved upon the knee implants designs made by them. Endotech's 'knee joint' was made of titanium, but titanium wears faster and, more importantly, is expensive. Invicta took Endotech design but produced a product using Cobalt–Chromium. Invicta's plant in the Ambattur industrial estate, Chennai, has a capacity to produce 2500 artificial knees.[15]

There are a few private agencies that develop customized knee implants, but none of them are registered manufacturers. In most cases, an imported model of the artificial knee joint is taken as the reference and the new model is developed using reverse engineering principles. Leading companies such as Depuy and Stryker have direct company-owned distribution agencies that take care of the implants supply in different parts of India. None of the leading companies that are mentioned in the above section have their manufacturing unit within India.

India does not have stringent medical devices regulatory policies in practice like FDA. This is also one of the reasons for the sluggish growth of the indigenous technologies.

## THE ARTIFICIAL KNEE MARKET SCENARIO

### The international market scenario[1,4,6]

With the growing desire of an ageing population to lead an active lifestyle, the global orthopaedic implant markets are poised for rapid expansion in the coming years. In 2007, the global population aged 65 and over is estimated to be 500 million and every year more than 800000 people are added each month to the pool of the world's elderly population. The growing population aged 65 and over opens door to growth opportunities for orthopaedic surgery.

**Table 1:** The global orthopaedic implants market by revenue

| *Year* | *Global orthopaedic implants revenue (US$ billion)* | *Global knee implants revenue (US$ billion)* |
|---|---|---|
| 2002 | 4.58 | 1.85 |
| 2003 | 4.88 | 2.00 |
| 2004 | 5.58 | 2.15 |
| 2005 | 5.95 | 2.32 |
| 2006 | 6.58 | 2.50 |
| 2007 | 7.01 | 3.25 |
| 2008 | 7.58 | 3.50 |
| 2009 | 8.08 | 4.18 |
| 2010 | 8.58 | 4.50 |

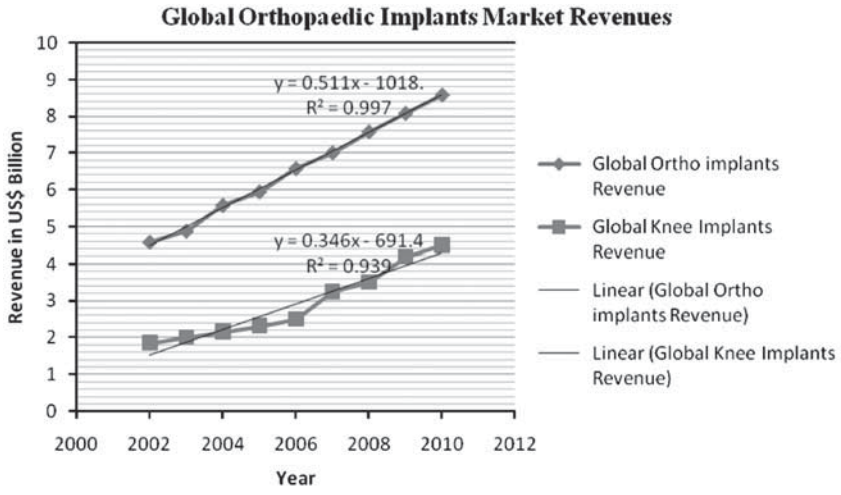


**Figure 1:** The global orthopaedic implants market by revenue.

Demographics coupled with technology advancement will be the key to growth of global orthopaedic implant markets. A number of technological innovations have been developed to increase the longevity of the implant. The new long lasting implants are expected to satisfy the desire of not only ageing population, but also younger patients to live active lifestyle. The orthopaedic companies are increasing spending on research and development to create implants that can last longer. The life of implants is very important, especially for younger patients who want to opt for reconstructive surgery.

Besides developing improved implants, companies are developing technologies to assist new implants as well as new surgical techniques. Technological advancements and demographics are expected to play a crucial role in not only developed but also developing countries. Increase in health-care spending in the developing countries is expected to influence growth in the orthopaedic implants markets. The growing target population coupled with increasing average selling implant prices is expected to result in high market growth in the next 5–6 years.

Table 1 and Figure 1 gives the market revenue for the global orthopaedic implants market and the artificial knee implants market with the forecast in revenues till the year 2010.

The global orthopaedic implants market had a revenue of US$7.58 billion in 2008 and a similar growth is expected till the year 2010 with an Compounded Average Growth Rate (CAGR) of 6.6 per cent. The global artificial knee implant market had revenue of US$3.5 billion in 2008 and a similar growth is expected till the year 2010 with a CAGR if 7.2 per cent.

The artificial knee implant market is dominated by international players as shown in Table 2 and Figure 2.

**Table 2:** Artificial knee market share analysis

| *Company* | *Knee implant revenue US$ million* | *Market share (%)* |
|---|---|---|
| Depuy | 575 | 23 |
| Zimmer | 725 | 29 |
| Stryker | 500 | 20 |
| Biomet | 275 | 11 |
| Others (Including Smith & Nephew, Wright and so on) | 425 | 17 |

## The Indian market scenario[12–14,16]

India is the best destination in the world for Orthopaedic Surgery. In India it is not

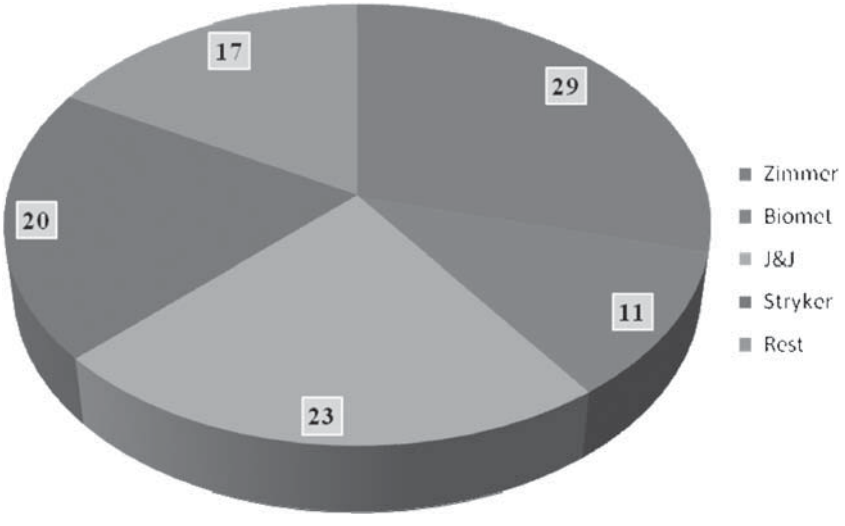


**Figure 2:** Market share analysis of artificial knee implants market.

  

only cost effective, but also it is healed and treated under best medical conditions. Shoulder/hip replacement and bilateral knee replacement surgery using the most advanced keyhole or endoscopic surgery and arthroscopy are done at several hospitals in India. Some hospitals in India have operation theatres with laminar air flow system, which compares with the best in the United States and the United Kingdom.

Medical tourism has become a common form of vacationing, and covers a broad spectrum of medical services. It mixes leisure, fun and relaxation together with wellness and health care. A combination of many factors has led to the recent increase in popularity of medical tourism. Exorbitant cost of health-care and medical facilities in advanced countries, ease and affordability of international travel, favourable currency exchange rates in the global economy, rapidly improving technology and high standards of medical care in the developing countries has all contributed their share to this rapid development of medical tourism.

Apart from the medical tourist who prefer to go for orthopaedic surgery in India, especially in the Total Knee Replacement (TKR) surgeries, the demand for knee surgery by the Indians are quite high but the market has not been well capitalized due to non-availability of indigenous cost effective technologies. According to a Frost & Sullivan report in 2006, India is one of the countries with large number of patients with arthritis. India has an annual demand of 50 000 artificial knees. This number is expected to grow at a very high rate.

## LIMITATIONS OF EXISTING MODELS

### Technical limitations[16–19]

There are about 150 models of artificial knee that are available in the market, but none of these models have been able to mimic the functionality of the natural knee.[12] As the artificial knee designs have been primarily based for patients over 65 years of age, stability has been the prime focus for designer over the past few decades. The decrease in the average age for patients undergoing TKA is noticed in the recent years. Younger patients are also undergoing TKA surgeries. It has now become mandatory that functionality of the knee implant is also given similar priority as that of stability.

The natural knee has 6 degrees of freedom (3 rotational and 3 translational). The artificial knee commonly used in TKA has only 1 degree of freedom (that is the flexion-extension movement). Newly developed artificial knee joints come with 2 degrees of freedom that can allow flexion-extension and internal-external rotation.

There is broad gap in the functionality of the artificial knee joints as 4 degrees of freedom are completely ignored. This can cause change in the gait pattern of the patient and also affect the post-surgical performance due to psycho-social factors.

### Economic limitations

The average cost of a knee implant is between $3000 (that is, Rs 150 000) and $7000. The average expenditure inclusive of the surgery and the implant is between $4000 and $10 000. This is far beyond the reach for the economic levels of an average Indian. The indigenous manufacturing of the implants can drastically bring down the cost of the implant. It is estimated that the cost rises up to 300 per cent due to import-export expenses.

## FUTURE OUTLOOK AND COST BENEFIT ANALYSIS

A survey by the National Institute of Health states that in the United States, as of 2006, the number of TKA per annum is around 300 000. In India, even though

the population is over a billion the number of TKA in a year is around 20 000 as of 2006. When considered as a proportion of the population (US about 300 million, UK about 60 million, India about 1.1 billion) this gives an indication of market potential.

There are many reasons for the lack of development of the Indian market. The first and foremost reason is the cost of the implant in relation to per capita income (India about $3000, US about $45 000, UK about $33 000, all calculated at purchasing power parity). Given the typical cost of a knee implant, this is the major constraint on market development.

The cost of TKR for one knee joint is about 170 000–180 000 rupees (INR), which includes the cost of the implant of Rs 80 000, your hospital stay which should be about 7–10 days, surgical and anaesthesia charges, or and consumable and so on. In some cases such as diabetes, in which the stay may be longer because of any reasons, the charges may be a little more.

According to a Frost & Sullivan report, the artificial knee market in India is approximately $200million in 2006.[20] It is estimated that the requirement for artificial knee in India as of 2007 is around 40 000 artificial knee joints per year. But the average number of TKA's in the country as of 2008 is only around 15 000–20 000 (Figure 3). We still have a 50 per cent of the demand unmet.

Out of the $200 million market value in India, about 90 per cent of the market is dominated by the imported knee implants by the leading players. Only 10 per cent of the demand is met by the Indian manufacturers. This condition is expected to get better in the coming years.

From Figure 4, it is evident that the majority of the market share for artificial knee in India is held by the global players. None of these global players have their manufacturing units in India. All these implants are basically imported from different countries where they are


**Figure 3:** Demand supply pattern of artificial knee in India.

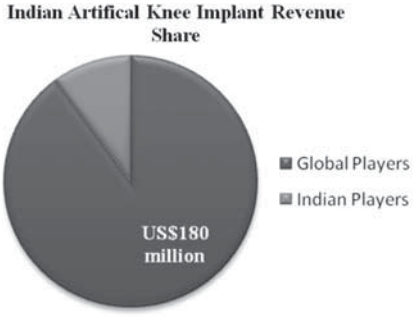


**Figure 4:** Indian knee implant revenue share.

manufactured. Importing these implants would mean a lot of money has to be paid as foreign exchange and taxes while getting them into India. These expenses are added to the original cost of the knee implant, which leads to the higher price point of these implants.

From the above section it is very evident that there is a very clear need for an indigenous knee implant, which if cost effective can take a clear lead in this market. Moreover, when the knee implant is made within the country, the cost of the implants can be made very much less than the present cost. This would in turn increase the accessibility of the knee joint surgeries for the middle-income group in India.

## CONCLUSION: THE NEED FOR AN INDIAN ARTIFICIAL KNEE

The artificial knees that are currently on the market are designed with reference to the western population. The western lifestyle generally does not include much of high

  

flexion activities. The average high flexion activity needed for a western lifestyle is around 85–90 degree of flexion extension.

In the Eastern world countries such as India, China and Japan, which form more than two-thirds of the global population, activities such as sitting on low platform, squatting and semi squatting becomes an integral part of their lifestyle. The artificial knee joints that are available in the market provide flexion range of 90 degrees, which is quite sufficient for living with the western lifestyle. But using the same knee joint in the Eastern world may not be appropriate in terms of functionality and post-surgical QoL of the patients. There arises a need for development of an artificial knee that can satisfy the needs of the Eastern world population.

So an optimized range of motion of 120 degrees would provide the patient with optimized functionality along with more stable knee joint.

Moreover, the TKA is gaining popularity off late and the standard per capita income of an average Indian is on the rise. Also the increase in the awareness on these kinds of surgeries will increase more number of patients to come forward for these surgeries in the next decade.

## REFERENCES


1 Raymond, P.R. (2005) The early innovators of today's resurfacing condylar knees. *The Journal of Arthroplasty* 20: 2–26.

2 Richard, S.L., Denham, R.A. and Apley, A.G. (1984) *Replacement of the Knee*. Springer-Verlag, Michigam: The University of Michigan, p. 3.

3 Scott, R.D. (1982) Duopatellar total knee replacement: The Brigham experience. *The Orthopedic Clinics of North America* 13(17): 85–92.

4 Scott, R.D. and Volatile, T.B. (1986) Twelve years' experience with posterior cruciate-retaining total knee arthroplasty. *Clinical Orthopaedics and Related Research* 20(5): 100–107.

5 Stiehl, J.B., Komistek, R.D., Dennis, D.A., Paxson, R.D. and Hoff, W.A. (1996) Fluoroscopic analysis of kinematics after posterior-cruciate retaining knee arthroplasty. *Journal of Bone and Joint Surgery-British* 77-B(6): 884–889.

6 Thomas, W.H. (1980) Duopatellar total knee athroplasty. *Orthopaedic Transactions* 4: 329.

7 Walker, P.S., Ranawat, C. and Insall, J. (1976) Fixation of the tibial components of condylar replacement knee prostheses. *Journal of Biomechanics* 9(3): 269–276.

8 Walker, S.A., Hoff, W., Komistek, R.D. and Dennis, (1996) 'In vivo' pose estimation of artificial knee implants using computer vision. *Biomedical Science and Instrumentation* 32: 143–150.

9 Wright, R.J., Lima, J., Scott, R.D. and Thornhill, T.S. (1990) Two- to four-year results of posterior cruciate-sparing condylar total knee arthroplasty with an uncemented femoral component. *Clinical Orthopaedics and Related Research* 260: 80–86.

10 Shimokochi, Y. and Shultz, S.J. (2008) Mechanisms of noncontact anterior cruciate ligament injury. *Journal of Athletic Training* 43(4): 396–408.

11 Utah Hip and Knee. (2009) http://www.utahhipandknee.com/history.htm, accessed 15 March 2009.

12 Sivarasu, S. and Mathew, L. (2007) 3D CAD conceptual design of an artificial knee. *Journal of Long-Term Effects of Medical Implants* 17(4): 313–320.

13 Sivarasu, S. and Mathew, L. (2008) Finite-element-based design optimization of a novel high flexion knee used in total knee arthroplasty. *Applied Bionics & Biomechanics* 5(2): 77–87.

14 Sivarasu, S. and Mathew, L. (2008) Artificial knee implant design parameters affecting the range of motion improvement after the total knee arthroplasty. *Journal of Long-Term Effects of Medical Implants* 18(4): 259–265.

15 Ramesh, M. (2009) Invicta getting big on artificial knees. *The Hindu*, http://www.thehindubusinessline.com/2008/04/12/stories/2008041252122100.htm, accessed 14 March 2009.

16 Sivarasu, S. and Mathew, L. (2009) Finite element analysis of a novel high flexion knee (Ti – UHMWPE) used in total knee arthroplasty. *The Internet Journal of Bioengineering* 14(1), http://www.ispub.com/journal/the_internet_journal_of_bioengineering/volume_4_number_1_56/article/finite-element-analysis-of-a-novel-high-flexion-knee-ti-uhmwpe-used-in-total-knee-arthroplasty.html.

17 Sivarasu, S. and Mathew, L. (2009) Kinematic analysis and three-dimensional finite element analysis of a mobile-bearing artificial high flexion knee. *Biomedical Engineering: Applications, Basis and Communications* 21(4): 279–286..

18 Sudesh, S. and Mathew, L. (2007) Design of an Artificial High Flexion Knee. Life Science Systems and Applications Workshop. LISA 2007. IEEE/NIH, 8–9 November, pp. 112–115.

19 Sivarasu, S. and Mathew, L. (2008) Artificial high – Flexion knee customized for eastern lifestyle. Proceedings of the 13th International Conference on Biomedical Engineering. ICBME 2008; 3–6 December, Singapore. Springer, IFBME Series, pp. 1497–1499.

20 Frost & Sullivan. (2009) http://www.frost.com/prod/servlet/market-insight-top.pag?docid=682560, accessed 14 March 2009.