Orthopaedics Surges Ahead

The year 2007 marked the 60th year of Indian Independence, but a sizable number of Indians are waiting to be freed from the gripping pain in their joints and bones. What these patients would like is to reduce, if not end their suffering and improve the health-related quality of life. This is exactly what the Bone and Joint Decade (BJD) — a multi-disciplinary international initiative supported by WHO, the World Bank and the United Nation aims to achieve. Currently, in its seventh year BJD has created a global platform to address the growing needs of the people affected with orthopaedic disorders. With its own chapter of BJD, India is playing its part in the struggle against these disorders. Though the results of these initiatives will be available after the stipulated period (2000-2010) is over, it might be interesting to note that there have been noticeable developments in this arena.

The advancements in the field of orthopaedics in India are in tune with the global progress, as the latest techniques and equipments to handle this probable epidemic are available here and today, world-renowned surgeons are practicing the latest surgery techniques in our hometown. However, it would still be a while before these new techniques and treatment reach the Indian aam aadmi. So far, the only hope for the aam aadmi is the expanding orthopaedic implant market, owing to the global giants setting shop in India. Accordingly, India is expected to be the forerunner in terms of research, treatment options and revenue generation in the orthopaedic segment, in the time to come.

The scope of the problem

According to international statistics, joint diseases account for half of all chronic conditions in people aged 60 years and over. Similarly, fragility fractures have doubled in the last decade and 40 per cent of all women over 50 years are prone to suffer an osteoporotic fracture. Globally, the number of hip fractures is expected to rise from about 1.7 million in 1990 to 6.3 million by 2050, unless aggressive preventive programmes are started.

To make matters worse, experts predict that the number of individuals over the age of 50 years is expected to double between 1990 and 2020, which will have a significant bearing on the burden of orthopaedic disease. Another, significant consideration is the steep increase in road traffic injuries, which are estimated to account for as much as 25 per cent of all healthcare expenditures in developing nations by the year 2010. Further, terrorism may add to this global burden with increasing incidence of violence being reported annually.

In spite of this, orthopaedic conditions do not receive the attention they deserve. "The lack of attention by the medical profession, policy-makers and the media is due to the perception that orthopaedic diseases are less serious. Unlike cardiovascular disease, AIDS and cancer, they are largely chronic, non-fatal conditions and tend to be seen as an inevitable consequence of ageing," says Professor Lars Lidgren, Department of Orthopedics, Lund University Hospital, Sweden and Chairman of the International Steering Committee, Bone and Joint Decade. Aging may be one of the reasons for increasing orthopaedic diseases, but it's not the only reason, an active lifestyle and high life expectancy also result in high wear of joints.

There is no study, which estimates the burden of major orthopaedic conditions in India. The WHO-ILAR (International League of Associations for Rheumatology) COPCORD (Community Oriented Program and Control of Rheumatic Diseases) study, projecting data of over 35,000 people surveyed in Jammu, Lucknow, Bhigwan, Pune and Chennai, by Dr. Arvind Chopra, sheds some light on the present scenario. The study states that 12-15 per cent of the Indian population seem to suffer from some form of painful rheumatic ailment and at least 55-60 per cent recorded a significant impact on their life, work and finances. About 50-55 per cent patients suffered from some form of soft tissue rheumatism (commonly back, knee, neck and shoulder pains) followed by degenerative disorders (osteoarthritis and spondylitis of knees and spines) in one third of the population. Inflammatory arthritis, including rheumatoid arthritis (often a progressive crippling and deforming disease), affects less than 10 per cent of the patients, but being a major treatment challenge attracts maximum attention.

Advances in orthopaedics

The discipline has seen a slow but steady progress in India over the years. Consequently, the orthopaedic market in India has witnessed a major boon, mainly due to the increased spending capacity of the Indian population.

Diagnostics has benefited from advanced immunological techniques, which gave a major advantage at accurate diagnosis and suitable therapy. The good old X-ray got a face-lift with enhanced illuminators and digitalisation. Imaging revolutionised by advances in CT scan and MRI, 3D imaging and Colour Doppler have enabled efficient treatment of deep-seated lesions (spinal/pelvic). Explains Dr. Nandkishore Laud, Orthopaedic Surgeon, Breach Candy Hospital, Mumbai,"It is possible today to obtain biopsies from deep lesion in spine, pelvis using CT scan images as a guide. This has prevented extensive exploration to diagnose and treat such lesions. The MRI scan with advancements, has helped to detect minor lesions, which otherwise were difficult to diagnose. MRI is also useful for further prognostication of benign and malignant bone tumours."
On the surgical front, main revolution is driven by minimal invasive approach aided by computer-guided surgery, which means less morbidity and lesser hospital stay for patients. Says Dr. Parag Sancheti, Medical Director, Sancheti Institute of Orthopaedics and Rehabilitation, Pune,"The accuracy in surgery can be increased by using computer navigation and longevity is increased by using better metals and polyethylene for prosthesis. Minimally invasive techniques are being used to improve the surgery outcome and also to enable the patient to return to work early."

With the availability of networking systems that link OR with facilities at different locations, supported with a range of integrated surgical equipment and lights, offer novel experience to the operating surgeons. These system are useful as they can exchange MRIs, X-rays, live pictures and other kinds of information between ORs, doctor's offices and teaching institutions located anywhere in the world.

What's more? Our own orthopaedic surgeons have gained considerable accolade and acknowledgement from their counterparts all over the world. They have even contributed to the field through research and innovation, like Dr. BB Joshi's indigenous External Fixator for deformity correction and muscle pedicle bone grafts for non union of hip fractures and Custom Mega Prosthesis for bone tumour by Dr. Mayil. V. Natarajan, HoD-Orthopaedic Surgery at the Madras Medical College & Research Institute and Government General Hospital, Chennai. Also, there has been a constellation of small but significant developments in the field that are bound to impact the way orthopaedics will be practiced in future, which are…

Botulinum toxin therapy

A new treatment modality gaining popularity in the UK is the emerging use of Botulinum toxin type A for the treatment of Cerebral Palsy adjunct to physiotherapy, splints and surgery according to a study published in the British Medical Journal.

The study states that the treatment is most effective in patients with dynamic muscle shortening that is localised to a few muscle groups. Experts believe that use of Botulinum toxin type A reduces the stiffness of muscles making them more amenable to stretching. This allows better ankle movement, increases the strength of antagonist muscles and results in a considerable improvement in walking. Though the technique has been successful in some patients, long-term results are still awaited.

Flexible nailing for stabilising long bone

Says Dr. Deepak Sharan, Consultant in Orthopaedics, Rehabilitation & Ergonomics and Medical Director, RECOUP Neuromusculoskeletal Rehabilitation Centre, Bangalore,"Emphasis on minimally invasive methods for stabilising long bone fractures like the flexible intramedullary nails or external fixators are one of the recent developments in paediatric orthopaedics." Flexible nails produced from new metal alloys are small enough to fit the intramedullary canal in children along with maintaining their shape after contouring and are strong enough to provide stable fixation. It is comfortable for the children and manageable for the parents. The indications for flexible nailing have now been extended to include unstable fractures of the tibia and forearm.

Autologous chondrocyte transplantation

Damage to articular cartilage has for long been a cause of concern, however with the advent of autologus chondrocyte transplantation there is greater potential for repair of these injuries. Researchers believe that transplantation of hyaline cartilage has been used for a number of years, but there are few sites where donor articular cartilage can be harvested without damaging the joint. Thus, only small articular defects can be treated with this method. However, an advancement in the procedure gave rise to a new patented technique, which allows small amounts of hyaline cartilage to be harvested, the chondrocytes extracted, the cell population increased in tissue culture and reimplanted at the treatment site. This technique in spite of being a lengthy process is less painful and is believed to aid faster recovery plus reduces morbidity in patients. Currently, at a nascent stage, the technique has already gained strong admirers in all parts of the world.

Material selection for implants The most desired feature of an orthopaedic implant is biocompatibility, besides exhibiting strength and load-bearing capabilities, as well as fatigue and corrosion resistance. In this regard, large diameter heads (metal on metal or ceramic on ceramic) offering patients more stability and higher range of motion allowing them to squat in select cases, has caught the attention of implant manufacturers."Improved designs of polymer in joint replacement will enhance the performance and longevity of joints for a longer time. Small stem hip implants are being used as they help conserve bone," says Dr. Sanjay Agarwala, Chief of Surgery, P D Hinduja National Hospital & Medical Research Centre, Mumbai. Further, titanium is gaining popularity as a choicest material for implants, as it is lighter and more corrosion resistant. Besides, various alloys are also being used for their higher strength and biocompatibility factor.

Molecular techniques in orthopaedics

There has been tremendous research in the area of orthobiologicals and growth factors. Their use mainly in fracture healing has been well established with the use of bone morphogenic proteins and transforming growth factor. Experts suggest that other factors, such as insulin-like growth factor II and platelet derived growth factor, are also important as they lead to increase in bone matrix. The use of these growth factors may stimulate fracture repair and minimise the rate of non-union. These substances have given hope to patients with bone tumour. Dr. H S Chhabra, Chief of Spine Service & Medical Director, Indian Spinal Injuries Centre and Chairman–Education Committee, Indian Science Communication Society, Delhi, elaborates,"Genetically engineered proteins are now commercially available for bone fusion surgery. This will eliminate the need for either autologous or allograft bone use and all of the potential morbidity and limitations inherent in these grafts."
Bone allograft

Cadaveric bone transplant has emerged as a treatment modality for bone cancer and trauma patients who are on the verge of handicap due to massive bone loss. Dr. Natarajan, a pioneer in the field opines that today it is possible to perform limb transplantation wherein cadaveric upper limb or lower limb can be transplanted to patients who have lost their limbs due to trauma or cancer. However, the lack of awareness among the masses has led to low bone donation further compounded by the lack of bone banks where cadaver bones and joints can be stored.

All these developments have taken place in conjugation with the developing orthopaedic market in India.

The other side of the coin

These futuristic projections along with unprecedented demand and changing needs have significantly transformed the Indian orthopaedic industry. Despite the fact that the market is highly fragmented and most of the implants are imported, the market has tremendous growth potential due to its substantial population base. According to an industry report published in Bone Zone in May 2006, the Indian medical devices market is valued at about US $1.5 billion, with an average annual growth rate of over five per cent. The market is largely dominated by hip implants, which comprise the largest share of the market over — 40 per cent, whereas trauma devices account for about 35 per cent and knee implants account for about 25 per cent. Says Julian Nair, Deputy Country Manager, Aesculap – B.Braun Medical Pvt. Ltd. "The present market for joint replacement in India hovers above Rs. 200 crore with over 40,000 joint replacements annually. This is expected to increase significantly with a CAGR of over 20-25 per cent in the next few years."

J&J enjoys a good market presence among the global players and was one of the first orthopaedic companies to set shop in India. Others like B.Braun, Stryker, Zimmer, Synthes and Biomet followed suit. "Most of them (MNCs) are beefing up the Indian arm of their organisations in contrast with their earlier business model where they operated through local importers and/or marketing agents," informs Sanjay Banerjee, Country Head, Zimmer India Pvt. Ltd. Consequently, the very nature of engagement of suppliers with customers is undergoing a transformation from one that has traditionally been transactional in nature to more strategic partnerships in spreading awareness, clinical and educational programmes for enhancing surgical skills.

Its not only the global players who are geared up to face the new challenges in the market, the local players are also responding to the awakening. Among the local players, Medical International, Narang Enterprises, Global Products Corporation and Uma Surgicals are the well-known names who enjoy a prominent presence mainly in the fracture fixation and spinal segments of the Indian orthopaedics market. Apart from these, there are more than 180 such manufacturers reported to be in existence. These are ranging from organised players — exporting to regulated markets with quality system certification, globally accredited agencies to small scale manufacturers of unknown quality.

The market drivers

While the huge population base is the single largest driver of the market in India, the under-penetrated silver age population (> 55years) ie, 7-12 per cent of the total population, represents the scope for growth in the market. Currently, a middle income family of four would incur between US $170-255 a year on healthcare, as compared to just US $43 in the last decade," points out Ivan D'Silva, Country Manager-India, Biomet UK Ltd.

Rising health insurance

Facilities further strengthen the spending capacity of the middle-income group. The healthcare insurance sector registered a 35 per cent growth in 2005-06 and provided cash-less facilities to over 4,600 hospitals (source IRDA)."This will significantly increase the affordability for orthopaedics implants and high value items, in turn boosting the market," infers Vishal Gupta, GM, Stryker India Pvt. Ltd.

The growing recognition of the competence and skills of Indian surgeons as well as the emergence of world-class hospitals in the corporate sector has provided a stimulus to medical tourism."The situation today is such that no one has to travel abroad for cutting edge technology or treatment. In fact, many people are flocking to India to get treated with the latest technology at a fraction of the cost!" explains **Dr. Kiran T Kharat, Consultant Joint Replacement Surgeon & Director Arthritis & Joint Replacement Unit, Ruby Hall Clinic, Pune**. In fact, medical tourism is also channelling the orthopaedic companies to the almost untouched domain of Africa, as Africans constitute a sizable portion of the foreign patients in India.

Market issues & obstacles

Most advanced countries have a special regulatory process for medical devices, which takes into account the special characteristics associated with medical devices and certifies it. India neither has a well-developed laboratory for certifying these implants nor regulatory guidelines for manufacturing or quality check laboratories for orthopaedic products. On the contrary, by an amendment to the Drug and Cosmetic Act of 1940, orthopaedic implants are now classified as drugs! As a result, the manufactures and importers, now have to register orthopaedic implants with the Office of the Drug Controller General of India, prior to import, manufacture or sale in the Indian market.

The amendment is looked upon as a step towards assured quality of products for Indian patients, though the success of the regulation is yet to be determined. Says Banerjee, "The regulation is ultimately expected to rationalise the number of suppliers in the Indian market with only quality conscious suppliers continuing to be present and the rest falling by the way side."

Future trends from therapy and technology perspective

Future in orthopaedics will involve better implants with smoother and harder bearing surfaces that do not wear out with time and do not generate particulate harmful debris. This coupled with smaller bone conserving implant design could be ideal, as it would make revision surgeries easy and less traumatising. According to Dr. Kaushal Malhan, Consultant Orthopaedic Surgeon, Wockhardt Hospital, Mumbai," In future, one could expect implants, which can be folded so as to make them smaller and allow them to be put in through small surgical exposures as well as foldable interpositional type prosthesis." Similarly, potential prosthesis could be loaded with a surface of cartilage that is grown from the patient's own cartilage and then embedded on a carrier that can be implanted. This will give back a cartilage covering to the joint rather than putting in new artificial surfaces and reduce the debris related concerns. Excellent techniques of biologic fixation of implants could be expected in time to come that would give predictable, quick and safe fixation for years, which can be reversed at any time to remove the implants easily and insert a new assembly if needed.

Minimally invasive surgical options for joint replacements, spinal surgeries and fracture fixation will gain increasing penetration driven by patient's desire for better cosmetics, minimal pain and faster rehabilitation, hospitals' and surgeons' need for increasing bed throughput. Further, the manufacturers could look at specialised instrumentation, which would allows access and exposure to joints through extremely small incisions and also special implants, which can be implanted through the same.

The use of computer-navigated surgery, as on date, is superficial in the country at best. However, this is expected to evolve in the medium term with the development of robotics-aided solutions eliminating the need for multitude of instrumentation usually required for orthopaedic surgeries.

Additionally, robotic surgery would be a welcome change in orthopaedics, allowing all critical steps of the procedure to be done more predictably and more accurately. Enhancement in computer navigation will be far more advanced than it is today with the help of better softwares. These will recognise the shape, size and alignment based on imaging so that there will be no need for a surgeon to manually feed information to the computer, since it increases the chances of error. It will eliminate the need for trackers, as the computer will be linked to a machine to produce the necessary bone cuts.

Subsequently, results of current research in tissue regeneration techniques should materialise in the market in the future, thereby eliminating or at least minimising the need for complex surgeries."These therapies born out of well validated research are very encouraging indeed! But what is needed is good record keeping (register) so that the long-term outcome can be studied," says Dr. Kharat. In future, India needs to work on its disease registry, as it would provide useful information related to the disease and performance of various treatment modalities. Emphasising on the fact Dr. Lidgren said,"The most important reason for a country to have a national register is to be able to have quality assurance, where the individual hospitals can compare their results with the aggregated national results from a number of hospitals. This will also be able to enumerate the inferiority of a particular implant and efficiency of the technique." Additionally, cost utility based on health economy measurement studies is another possibility where these registries can be used.

Research in orthopaedics has not many takers in India, as it is an expensive preposition and requires huge infrastructure support. India could exploit its intellectual reserve and abundance of medical cases to feature in the global orthopaedic research scenario. In future, this latent but highly potential field could develop with the help of the corporate sector.

Finally print and visual media and Internet will increasingly play an important role in disseminating information and awareness to patients and their family members. There is a growing trend among patients and family members to seek alternate opinions and ask specific product-related queries of their surgeons prior to decision-making. The task for orthopaedic implant suppliers and healthcare service providers is therefore clearly defined — to create awareness and make patient-surgeon communication effective.