OrthoCAD Network Research Cell

संगणक सहायित विरुपशोधन जालक्रम अनुसंधान कक्ष

Orthopaedic Reconstruction

The OrthoCAD Network Research Cell was established in 2007 to jump-start indigenous research and development activities in orthopaedic reconstruction systems. It is supported by the Office of the Principal Scientific Advisor to the Govt. of India, New Delhi. The R&D team comprises mechanical engineers, orthopaedic surgeons and materials scientists from:

- Indian Institute of Technology Bombay, Mumbai
- Non Ferrous Technology Development Centre, Hyderabad
- Tata Memorial Hospital & Hinduja Hospital, Mumbai

The OrthoCAD Network addresses a critical need for mega-prostheses to reconstruct massive gaps or loss of bone from osteo-sarcoma (cancer), congenital (birth) defects or trauma (accidents). Osteo-sarcoma is mainly observed during growth spurts in children, and primarily occurs in long bones such as the femur, near the knee joint. Limb amputation in such cases results in life-long handicap. Mega-prostheses provide a superior physiological and psychological solution. Imported prostheses designed for the Western population are not suitable for the anatomy and functionality required by Indian patients and are unaffordable to the majority of our population.

The OrthoCAD team has developed a modular rotating-hinge total knee prosthesis suitable for Indian population, and evolved a manufacturing route to achieve high quality and economy. The prosthesis components are available in a range of sizes, which can be inter-changed to match the anatomy of a particular patient. The design has been validated by an integrated approach combining computer aided analysis, rapid prototyping, and knee simulators. The manufacturing route combines rapid pattern fabrication, investment casting, CNC machining and super-finishing to achieve high geometric fidelity, smooth finish, and superior properties. Innovative instruments, such as femoral jig and tibial jig have been developed to ensure ease, speed and accuracy of prosthesis implantation. A 3D surgery planning software ensures correct part selection and accurate implantation. Several major hospitals in India have come forward for the clinical trials of the prosthesis.

R&D Facilities

The networked facilities at IIT Bombay and NFTDC Hyderabad enable the team members to work seamlessly and concurrently through the stages of implant design, analysis, manufacturing and testing in close collaboration with medical professionals.

Facilities at *IIT Bombay* :

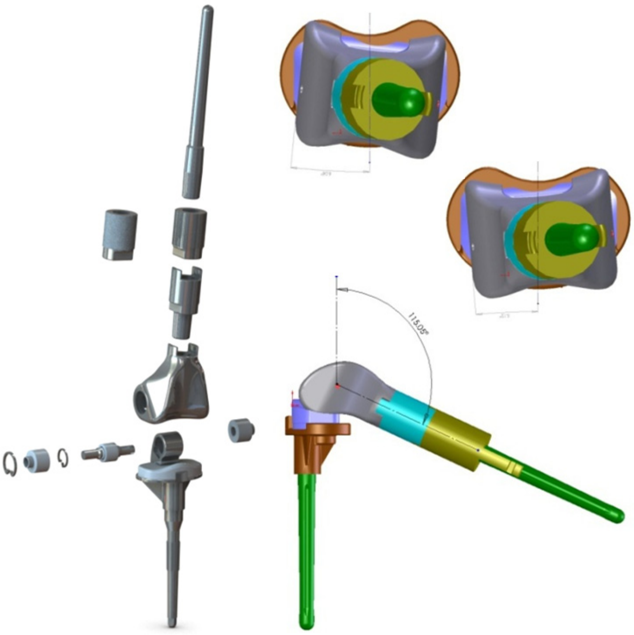
- Computer-aided Design (CAD): HP XW 8600 workstation with SolidWorks, Hypermesh and Radioss.
- Computer-aided Manufacture (CAM): HP 4400 work-station with AutoCAST-X and UG NX + CAM.
- Computer-aided Surgery (CAS): Quad-Core workstation with MIMICS and FreeForm
- Rapid Prototyping (RP): Solidimension SD300, with build size of 220x120x160 mm
- Knee Walking Simulator: Loading capacity of 4500 N and cycle time of 2-3 seconds
- Microscope: Meiji stereo microscope
- Weighing Balance: Sartorius balance, 0.1 mg accuracy
- Universal Testing Machine: Instron system with special-purpose attachments for implant testing
- Photo-elastic Stress Analysis: Vishay polariscope with laser direction indicator and coating kit
- Surgery Navigation Camera: NDI Polaris Vectra system with 1.5x3x2.4 m work volume

Facilities at *NFTDC Hyderabad* :

- 3D Scanning and CMM: FARO laser scanner, Geomagics
- CAD/CAM: ANSYS, LSDYNA, Unicam and Hypermill
- 4/5 Axis CNC Machines: Makino S33 VMC-2; machining centres
- Rapid Pattern Making: Stratasys Vantage
- Investment Casting: Shell making, stuccoing, dewaxing, melting and pouring.
- Centrifugal Casting: Top Cast system
- Plasma Coating: Sulzer-Metco
- Materials Testing & Characterization: Micro-hardness, UTM, SEM, ICP, AAS, UV, XRD, XRF, corrosion potentiostats
- Biological Materials, Cell Culture and Tissue Engineering: Ti, porous ceramic materials and perfusion cell cultures.

Prosthesis Development

The tumour knee prosthesis (TKP) is designed to provide the desired functionality (movements and load-bearing), and match the anatomy of Indian patients. A novel constrained rotating hinge has been developed, for flexion-extension movement of over 120 degrees, and rotational movement of +/- 5 degrees. Other main components include femoral condyle, tibial tray, tibial poly, femoral extension pieces, femoral stems and tibial stems. The femoral condyle is anatomically shaped to allow articulation of the patella on the anterior side. The rotational movement about the vertical axis is smoothly constrained by the special shape of the tibial poly fitted on the tibial tray. Hyperextension and hyperflexion are prevented by locking actions of the condyle on the tibial poly. Metal-to-metal contact is prevented by polymer bushes. Femoral and tibial stems are joined to the femoral condyle and tibial tray, respectively, by Morse tapers, which provide a tight fit, and at the same time allow revision if needed. Femoral extension pieces are used between the condyle and stems for reconstructing longer gaps in bone. The prosthesis is anchored in the bone using stems, which are inserted in the canal of both femur and tibia.

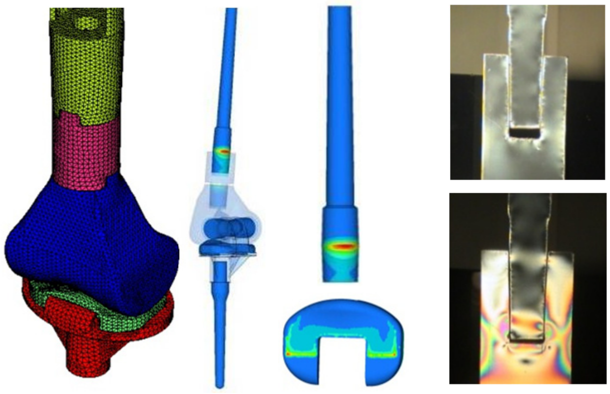


A morphometric study of over 200 patients from all over India was carried out to determine the correct sizes and shapes to best match the population. The condyle and tibial tray are designed in three sizes: small, standard, and large. The stems are available in a range of diameters ranging from 9 mm to 15 mm. The extension pieces are available in 10 mm length steps. Inter-changeability of components allows a very large number of combinations. This enables better anatomical matching and inter-operative freedom compared to a single standard prosthesis. It is also more economical than customised prostheses, which have a long lead time for manufacture.

Proven bio-materials are used to ensure long life (minimum wear and fracture), along with low weight. The condyle is made in cobalt-chromium-molybdenum alloy, stems are in titanium-aluminum-vanadium alloy, and polymer parts are in ultra high molecular weight polyethyene. Stem collars are coated with hydroxy-apatite for bone in-growth on prosthesis.

Evaluation and Testing

The anatomical and surgical suitability of the TKP have been evaluated by several iterations of computer simulation and rapid prototyping, followed by feedback from orthopaedic oncology surgeons at Tata Memorial Hospital.



The static strength of the prosthesis has been evaluated by applying virtual loads and simulating the stresses and strains using Finite Element Method (FEM). The method itself has been standardised by validating the results using experimental set-ups such as the 3-point bending test. A second set of experiments, based on photo-elastic stress analysis, further validate FEM results. This approach has significantly reduced prosthesis development time without compromising safety.

Many knee prostheses fail over a period of time due to loosening, wear or fatigue fracture inside a patient's body. To evaluate the dynamic safety and life of the prosthesis, novel indigenous knee walking simulator machines have been developed by the project team. The prosthesis is mounted on the machine and subjected to flexion-extension movements along with dynamically varying loads as per the walking gait, in conformance with ISO 14243 standard. The prosthesis has successfully withstood more than a million cycles of dynamic load at the rate of 1-2 seconds per cycle.

Prosthesis Manufacture

The anatomically critical geometry of the condyle is fabricated with high accuracy yet economically by a combination of advanced processes at NFTDC. A master model is produced directly from the CAD model of the condyle on a rapid prototyping machine. This is used to prepare a silicon rubber mold, from which a number of wax patterns are produced. These are used for making shell molds, into which molten Co-Cr-Mo alloy of the correct composition is poured under gravity or pressure. The dimensional variations have been studied to optimise the master geometry and process parameters.

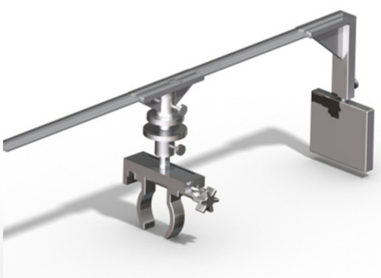
Other critical metal components, including those in Ti-6Al-4V alloy, are manufactured on 4-axis CNC machines and machining centres. The cutting tool path is optimised using computer-aided process planning software. This is followed by ultra-high surface finishing operations. The machining of polymer parts was also optimised after a series of experiments to obtain the desired surface finish and tolerances.

The components are inspected using spectroscopy (for composition), 3D laser scanning (for geometry) and surface probing (for roughness). A plasma-spraying facility has been created to coat the collar of the femoral stem with hydroxy-apatatite (HA), which encourages bone in-growth onto the prosthesis and further extend its life. The entire manufacturing route is being continuously improved and optimised.

Surgical Armamentarium

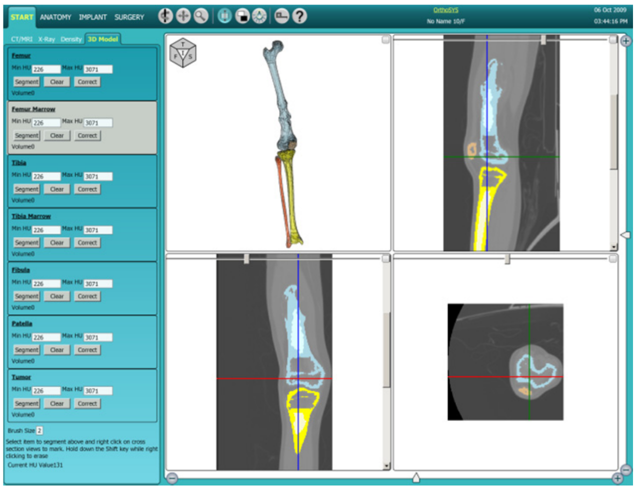
The armamentarium for total knee surgery comprises several sophisticated instruments to correctly resect the bone and properly anchor the prosthesis in the remaining bone. These instruments are designed for ease of use (compared to existing instruments), and ensure accurate outcomes.

The OrthoCAD team has developed two improved devices: femoral jig and tibial jig. These jigs enable cutting the femur and tibia bones in a plane exactly perpendicular to the bone canal. This ensures exact fit of the prosthesis (preventing undue stresses), and proper walking gait of the patient. Other standard instruments for total knee replacement include reamers, wedges, impactor and bone cement injector.



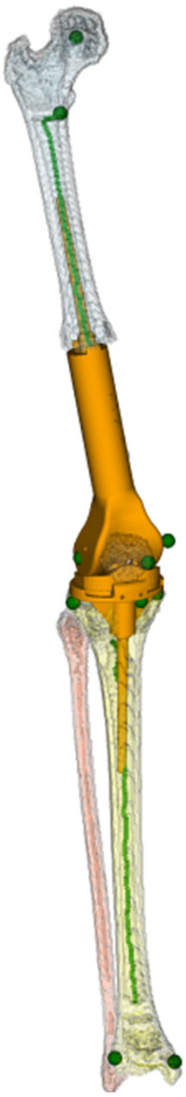
Surgery Planning

Orthopaedic reconstruction surgery requires high precision, and takes several hours to complete. Computer-aided surgery planning improves the accuracy of outcome and reduces the time involved. This is performed on a 3D computer model of patient's anatomy reconstructed from CT scan images.



An integrated software program called OrthoSYS has been developed for model reconstruction, 3D visualisation, tumour resection planning, prosthesis components selection, and their correct positioning. These functions are semi-automated by developing geometric reasoning algorithms for identification of anatomical landmarks, quantitative evaluation of deformities, and bone thickness analysis. Anatomical landmarks are localised and labelled without user intervention based on their geometric characteristics. Bone deformities are measured with respect to anatomical and mechanical reference axes. Prosthesis components are categorised as 'most suitable', 'probably suitable', and 'not suitable' for a particular patient, to minimise inventory. The prosthesis is automatically positioned in the resected bone model based on landmarks and reference axes; it can be interactively changed by the surgeon if needed.

The software prevents the use of under- and over-sized components for a given patient, and identifies extremes of size and shape that may require either custom components or special fixation methods. It is also useful for protocol evaluation, surgeon training and patient education.



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The Future... is Here

Medical device development requires multi-disciplinary inputs including 3D medical modelling, biomechanics, CAD/CAE/CAM, biomaterials, advanced manufacturing, and testing. Cutting edge technologies, equipment, and web-based conferencing are employed to compress the development time. The know-how is being shared with other interested groups in India and overseas. Much work is needed in developing other medical devices, economical manufacturing routes, comprehensive evaluation protocols, surgical instruments, pre-op planning and navigation. A new generation of medical engineering professionals is getting motivated through training courses, publications, conference presentations and exhibitions to explore this exciting field, which has immense potential for research, development and social impact.

Collaborative engineering class for medical device innovation at IIT-B

OrthoCAD booth at Techfest, Asia's largest technical exhibition in IIT-B

OrthoCAD Team (left to right): Rupesh Ghyar, Nagsen P, VK Suri, Neeraj Sinha, B Ravi, Shishir Rastogi, Manish Agarwal, PP Kotwal, K Balasubramanian, G Bhuvaneshwar, K. Subburaj, Nirmal Panda