





Surface Metrological and Computer-Aided Designing of a Tibia Bone for Region-Specific Implants

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Abstract. Load bearing joints such as knee and hip are the most-prone joints of osteoarthritis. Predominantly, Total Knee Replacement (TKR) and Total Hip Replacement (THR) are done to repair the affected knee and hip joints and reconstructed with metal implants. Proper implant fitting to the patient will avoid further revision surgeries. But, the loosening of implant is the major problem due to the unavailability of suitable implants. Implant manufacturers have designed the implants mostly with respect to the certain region-based population pool data. Most of the time, these implants don't fit for other region's people, creating implant loosening problem that leads to revision surgeries. Therefore, this research was aiming at designing region-specific implants with respect to regions. To retrieve the morphometric data from the regions, there is a need for efficient method to measure bones and create Computer-Aided Design (CAD) models. Tibia was taken as the subject for measurement to check for proper method to retrieve dimensions. Coordinate Measuring Machine (CMM), contact mode was used to extract the dimensional data. Since tibia bone is a complex-shaped object, reverse engineering technique was used to develop a fixture box with an aid of Three-Dimensional (3D) printer, to hold the tibia bone for measuring its complex features in eight planes (0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°).

The measured data of eight planes were used with the careful usage of pre-processing, registering and merging tools, to generate the master point cloud. The master point cloud was used as base with the integration of CAD tools to design 3D modelling of tibia. A comparative analysis was done between original tibia model and the 3D CAD model. Deviation analysis between the master point cloud and the 3D model was also done and the error was minimal (0.314274 mm). Thus, this work gave accurate results for using alternate scanning system other than Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) for the measurement of bone. This method can be used for retrieving bone dimensions from bone samples obtained from various regions for generating region-specific implants.

Keywords: Complex-shaped object, Tibia bone, Fixture box, Point cloud, CAD modelling.

DOI: <https://doi.org/10.14733/cadaps.2020.921-935>

1 INTRODUCTION

Pain in most joints is caused by three types of arthritis: osteoarthritis (OA), rheumatoid arthritis, and post-traumatic arthritis. With our aging population, the prevalence of osteoarthritis in the "developed" world is expected to increase. It is anticipated that, osteoarthritis will become the fourth leading cause of disability in the coming decades. The hip and knee (load-bearing joints) are the most likely targets of osteoarthritis. Hence, Total Knee Replacement (TKR) and Total Hip Replacement (THR) surgeries are increasing in number nowadays [18],[23].

In TKR and THR surgeries, entire bone was reconstructed and replaced with the metal implants. These implants should properly fit to the patient knee/hip. However, due to implant mismatching patient affects with severe pain leading to revision surgery. Number of revision surgeries after primary surgeries are increasing due to implant mismatch with the patients. Most of the manufacturers of implants have designed the implants with respect to the population of particular races (western). Therefore, markedly-available implants have posed many problems (loosening, swelling, etc.) after surgery as well thereby it has led to revision surgery in other regions. So, there is a need for designing region-specific implants and to provide large number of options for implants that to have better fit to the patients with respect to the population of races/regions to avoid revision surgery. This will help patient to have live their life as better day-to-day [11-13],[15, 16],[19].

Non-contact methods such as Computer Tomography (CT) scan and Magnetic Resonance Imaging (MRI) scan requires human living subjects for measurement. Medical CT scanner is developed more for quality viewing than for measurement point of view. The 3D model obtained using CT is slightly larger due to lower contrast problem. And 3D model obtained using MRI is smaller than the real bone. For measurement, accurate systems were needed, therefore alternate measurement systems were considered. In that Co-ordinate Measuring Machine (CMM) has good accuracy among the contact measurement systems.

Tibia, a complex-shaped bone is taken as an object to be measured. Tibia is a load-bearing bone of the lower limb. Measurement of tibia is needed for stature estimation, age estimation, sex determination, gait reconstruction, implant modelling, pre-surgical planning and biomechanical load calculation [22]. To design region-specific implants, there is a need for retrieving morphometry features from the tibia bone. The features are tibial anteroposterior length, tibial lateral anteroposterior length, tibial medial anteroposterior length, tibial circumference, tibial mediolateral length, and tibial aspect ratio. Mean measurement value for all the features have to be used for designing region-specific implants for different ethnicity. To retrieve the feature details, there is a need for 3D modelling of the tibia bone. To obtain the 3D model of tibia bone from the tibia samples, an accurate method for data acquisition and 3D modelling is required. Therefore, in this work, we have formulated the 3D modeling approach to design the tibia bone [8]. Motivation has come by using Additive Manufacturing (AM) as a tool to fabricate the fixture for holding the tibia bone to measure the geometrical features by contact mode CMM.

AM/Three-dimensional Printing (3DP) can be defined as "a process of joining materials to make objects from 3D model data, usually layer upon layer, as opposed to subtractive manufacturing methodologies" [1]. The AM has a significant impact on the design and manufacturing sector with its wide applications (aerospace, automotive, medical, defense, etc) and has good market potential. Recently, a study was performed to show 3DP as a potential technology to make the complex-shaped products or prototypes [3],[6],[7],[20],[21],[24],[25].

CMM can be used for extracting 3D data of the existing components either by contact or non-contact method. When a complex-shaped product is subjected to measurement, CMM is facing challenges to keep move/rotate according to the measurement requirement. In order to overcome the challenges in relevance to the measurement, customized/site specific fixture is needed. So that, the fixtures can be used as an aiding tool for measuring the complex-shaped product and extract the data using CMM in more accurate manner. Fixture is a structural object which can hold the predefined workpieces for aiding the measurement process in an accurate manner. The fixtures can be classified with different groups such as base plate device, fixturing element, supporting device and connecting device [9].

CMM is used to measure the complex-shaped object and at the same time, the process is tedious which needs pre-processing and registration of the measured data for generating the CAD-based modelling. The limitation of CMM is that, it can be able to trace only one surface at a time if the probe is fixed without any orientation. Therefore, generating a 3D model using CMM data that needs measurement on several planes and further these plane's data need to be merged into a single point cloud [14]. Then, the obtained point cloud can be effectively used for CAD modelling of the complex-shaped object.

Other kinds of scanning systems like laser-based scanning systems are available in the market. But, reflective objects cannot be measured properly using laser source system. Comparatively, accuracy is higher in CMM systems than other scanning systems. All kinds of objects (reflective and non-reflective) can be measured using CMM contact probe.

In this work, tibia bone was taken as an object to use a customized fixture and CMM (both contact and non-contact) for generating the geometrical data. This geometrical data's were further pre-processed, registered and merged to generate the complete 3D CAD model. Comparative analysis between original tibia model and the generated 3D CAD model was done. Deviation analysis between point cloud and the final mesh was done for finding any deviation in the final model. The methodology, results and discussions are presented in the following sections.

2 DESIGN AND DEVELOPMENT OF A FIXTURE BOX

Measurement of the geometrical characteristics of any object using CMM that needs a fixture to hold. Due to the complexity of the complex-shaped object, a customized fixture is needed. When a complex-shaped object is subjected for measurement, the designing of parts of the fixture box with respect to the complexity (size and shape) of complex-shaped object is needed. For that, some initial reference to designing of the parts using CAD software is normally involved. In addition to that, some of the analog-based measuring instruments are used to measure some of the features of complex-shaped object. These measured values can be used as a reference for making an acceptable CAD models of the parts that involve in fixture designing. The flow of the entire design and development of the fixture box in relevance to the complex-shaped object measurement is shown in Fig. 1.

In our earlier work [17], fixture box was designed and developed for complex-shaped femur bone and procedure was explained in detail. First level of measurements were done with only four planes of femur bone without any measurement principle. No merging operations were done due to less number of points. Only surface models were generated, 3D CAD model of the femur bone was not generated in that work [17]. In this work, tibia bone was taken for CMM measurement which is having more complex shape than femur bone. To generate a 3D CAD model of the complex-shaped object like tibia bone using CAD software, there is a need for surface points of the tibia bone. Phantom model of tibia bone was procured for the measurement process. For measuring the surface points of the phantom model of tibia bone using CMM, it has to be oriented to different angles for the measurement process. All the sides of tibia bone need to be measured at a specific angle to obtain the surface points which can be later used for CAD modelling of the tibia bone with respect to the specific angle. In order to rotate the tibia bone to a specific user defined angle and to hold it rigidly in a fixed position, a fixture box (Fig. 2.) with rotating holder was used.

The fixture holder specifically for the holding tibia bone was designed using CAD software and developed using 3D printer with Polylactide (PLA) material. Largest circumferential diameter of the tibia was taken as a reference for designing the holder for the bone. The assembled fixture box with specific holder for tibia bone was shown in Fig. 2.

3 MEASUREMENT PRINCIPLE FOR TIBIA BONE MEASUREMENT USING CMM

Measurement of any object using CMM should follow some measurement principle. Measurement principles of CMM are selection of proper probe, selection of workpiece orientation, stylus configuration, number and position of measuring points and direction and speed of the probe [4].

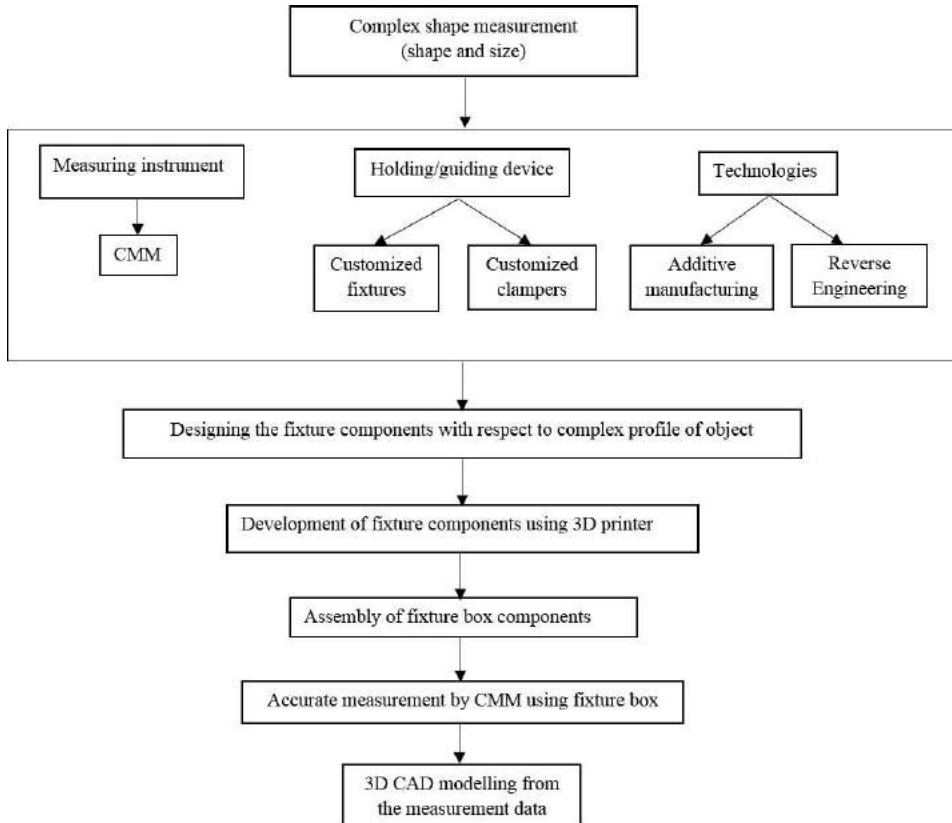


Figure 1: Flowchart for the complex-shape measurement process.

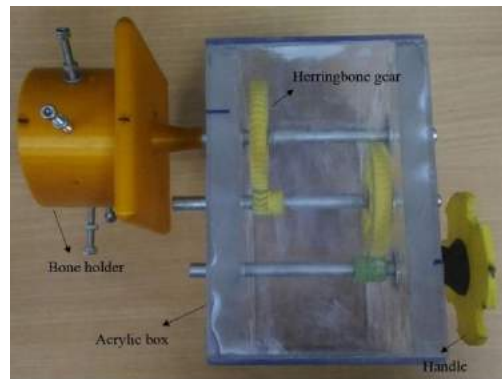


Figure 2: Assembled fixture box for tibia bone measurement.

Startup cycles, Stylus configuration and probe qualification were done. ISO 10360 series of standards [5] were performed to ensure CMM measurement that it is within the permissible error of length measurement (distances, diameters and position tolerance). The error bound for zeiss O-inspect CMM is given as

$$E_0 = 1.9 + \frac{L}{250} \quad (3.1)$$

The test values are checked for errors that are within the limit. If the test values are not great than the E_0 , then the CMM was verified. Calypso software, measuring software of Zeiss O-inspect CMM that has pre-written software for the calibration of probe. The indicated values of error were corrected using calypso software. So, qualification, verification and calibration were done before the measurement of bone.

Orientation of the measuring object should always within the work volume of the CMM. So, the tibia bone was oriented by fixture box within the work volume of CMM. The CMM work table usually can withstand within threshold weight. Heavier objects used to deviate the geometry of the machine thereby induce errors in measurement data. So, fixture box was designed and developed using 3D printer with PLA material which is having light weight comparing to the metal fixtures. The fixture box with tibia bone have less weight than the threshold weight fixed by CMM manufacturer. Clamping of tibia bone was done without any distortion. The six point clamping was done at the end of the distal tibia away from the measuring area site. The 3 mm diameter probe (ball type) was used for measurement. Probe calibration was done with respect to the reference of sphere.

The number of measuring points on the object depends on the defined geometric features such as planes, circles, straight lines etc. There was a standard for mathematically defined minimum number of measuring points for the defined geometric features. For example, 2 points can define a line. Usually, more than mathematically defined minimum number of points should be taken to ensure accuracy. But, complex-shaped like tibia bone do not have defined geometric features. Uniform way of measuring points do not work for complex-shaped object. Random way of measuring points with respect to complexity in different areas of the complex-shaped object has given accurate results [4]. So, more number of points were measured in complex regions than simpler region. So, the points were marked over tibia bone with respect to the complexity of tibia bone was used as reference for the measurement process. The zig-zag path was followed for measurement with forward measurement step pitch of 2 mm in simpler region and 1 mm in complex region and side step measurement pitch of 2 mm in simpler region and 1 mm in complex region as shown in Fig. 3.

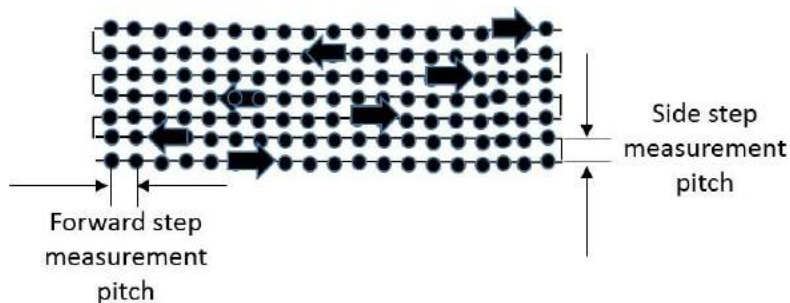


Figure 3: Measurement procedure.

4 EXPERIMENTS

Zeiss CMM (O-inspect 442) was used for measuring the dimensions of tibia bone. Both contact and non-contact measurements were used. The contact measurement was done using contact probe and non-contact measurement was done using Charge Coupled Device (CCD) camera with laser pointer. This CMM has the work space of 400 mm × 400 mm × 200 mm. All the points measured with both contact probe and non-contact camera were exported as text files using Calypso software. The Zeiss CMM was used for the tibia bone measurement (Fig. 4.).

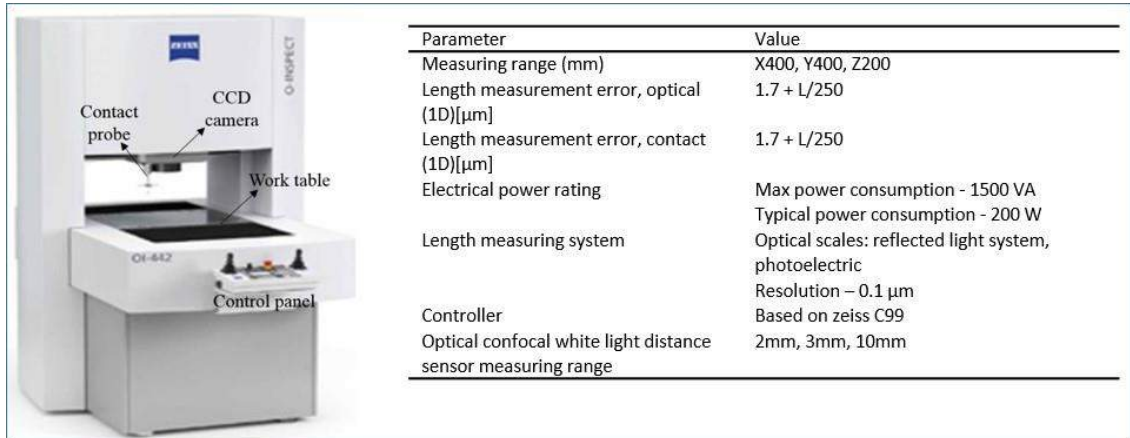


Figure 4: Zeiss O-inspect 442 CMM with its parameters.

4.1 Non-contact Measurement of a Tibia Bone

Non-contact measurement (Fig. 5) was done using a CCD camera that was available with the CMM. Tibia bone was placed on the CMM table and the camera has taken the data points. From that, the outer profile of the tibia bone was measured. Surface features were not able to measure using the CCD camera. All the surface points were measured using the contact probe. The outer profile of the front side of tibia and back side of tibia were measured by moving the camera in X, Y and Z directions. The pdf files of the data were exported using Calypso software for further processing.

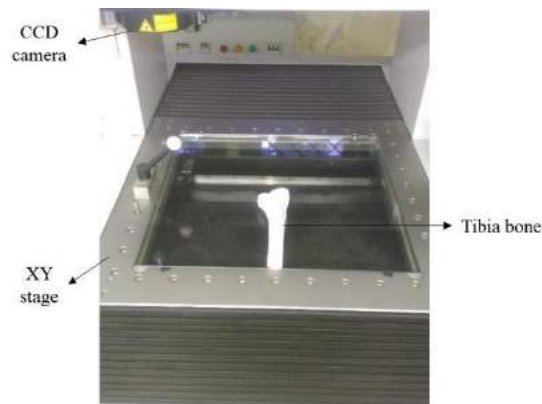


Figure 5: Non-contact measurement of tibia bone.

4.2 Contact Measurement of a Tibia Bone using Fixture Box

Tibia bone phantom model was used for the measurement. Points were marked all over the tibia bone surface for measuring with contact probe (Fig. 6(a)). Measurements were made at 0° , 45° , 90° , 135° , 180° , 225° , 270° and 315° planes by rotating the holder with handle. All the measurements were made at 0^th plane with tibia bone oriented to respective degrees. All the marked points were measured manually with contact probe and recorded with respect to scanning path. The scanning path for 0° plane of tibia bone using fixture box is shown in Fig. 6(b). Likewise, scanning path for other planes were followed after rotating tibia bone to respective angles. While measurement process, one point common to both the planes (0° and 45°) in the lower most scanning line was chosen as origin point (point correspondence) and measured in both the plane measurement for

merging procedure during the CAD modelling. Likewise, one point common to other pair of planes were chosen as origin point and were measured. Those point correspondences will be used in merging process of all plane measurement data. Measurement set up is shown in Fig. 7. Calypso software was the measuring software. The collected data points were exported as pdf files by the calypso software.

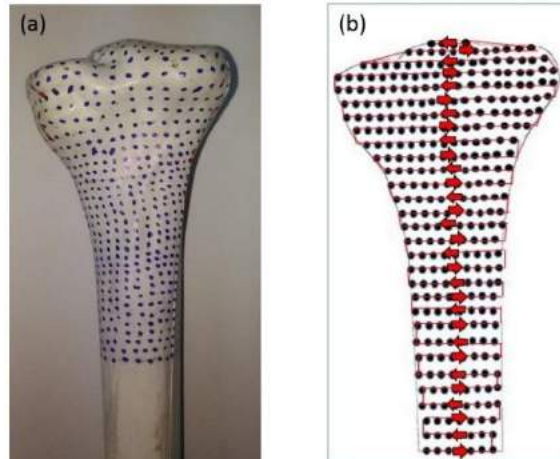


Figure 6: (a) Tibia bone with points marked over it for measurement, and (b) Scanning path followed during contact measurement for 0° angle.

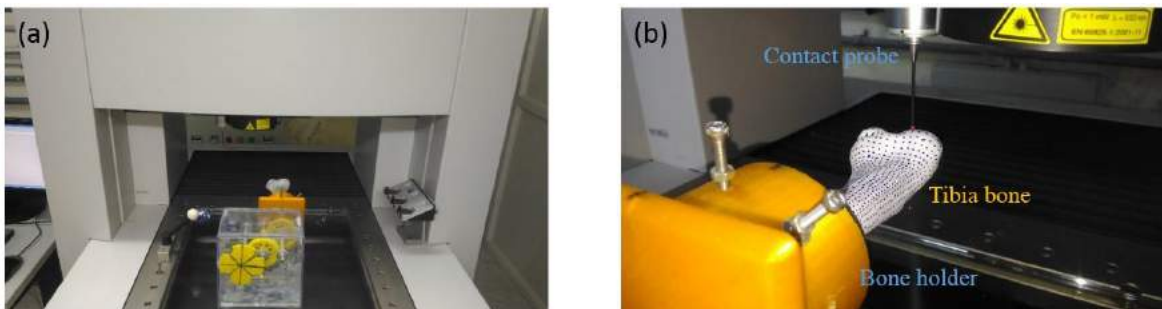


Figure 7: (a) Measurement set up for contact measurement using CMM, and (b) Contact probe tracing the scanning path.

5 RESULTS AND DISCUSSIONS

5.1 CAD Modelling from Non-contact Measurement

The pdf files were converted to excel files to remove erroneous points for filtering them as manually. Then these files were imported to Solidworks for the CAD modelling. The 3D splines were created using 3D sketch. Then these splines were converted to surfaces using boundary surface technique. The obtained surfaces were combined using knit feature in Solidworks. Since profile points of the front and back side of the tibia bone were obtained, only surface models of front and back side of the tibia bone were obtained. Two surfaces which were obtained could not be able to be merged, as surface features were not measured using CCD camera. The surface models of the front and back side of the tibia bone are shown in Fig. 8.

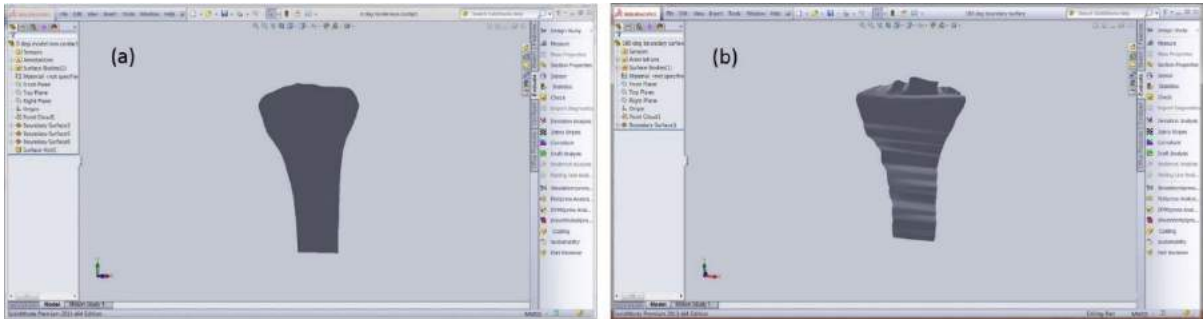


Figure 8: Surface models: (a) front view of the tibia bone, and (b) back side of the tibia bone.

5.2 CAD Modelling from Contact Measurement

5.2.1 Preprocessing and registration of point cloud data

The point cloud data which were obtained has several erroneous points and all the measurements were done in 0th plane but oriented to their respective degrees. So that, there is a need for preprocessing of the data points. While taking the data point's manually using CMM contact probe, there were erroneous points recorded which have affected the 3D CAD modelling hence these points have to be removed. There were eight different points cloud which were measured at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° rotations of the fixture box, respectively. Preprocessing steps like data acquisition, noise removal and format conversion were done. Calypso software was used to export the point cloud as pdf files. These pdf files were converted to excel files for manually removing erroneous points like 2D line points. After filtering, the excel files have been converted into text files. These text files again imported to CAD software for further processing. The flowchart for preprocessing and registration of the point cloud is shown in Fig. 9.

Registration process involves transforming all the plane measurement data to their respective degrees and to have common frame of reference. As all the measurements were made at 0th plane, there was a need for point cloud orientation. Each point cloud was oriented to their respective degrees about Y-axis using the rotation parameters in mesh preparation wizard of Solidworks. As 0° measurement was the default setting, there was no need of orientation for the point cloud obtained at 0° angle of the fixture box. For 45° rotation of the tibia bone using the fixture box, it was needed a -45° orientation of the point cloud for the original position. Likewise, all the plane measurement data were transformed to their original orientation as shown in Tab. 1.

Plane measurement data	Orientation angle (rotation parameter value)
0°	0°
45°	-45°
90°	-90°
135°	-135°
180°	-180°
225°	135°
270°	90°
315°	45°

Table 1: Transformation of a point cloud.

While doing measurement at various degrees, one common point to 0° and 45° point cloud was chosen as origin point (point correspondence) and measured in both the plane measurements. In 0°

point cloud, that point was chosen as origin and other points were 3D marked with respect to the origin and exported as text files using macro.

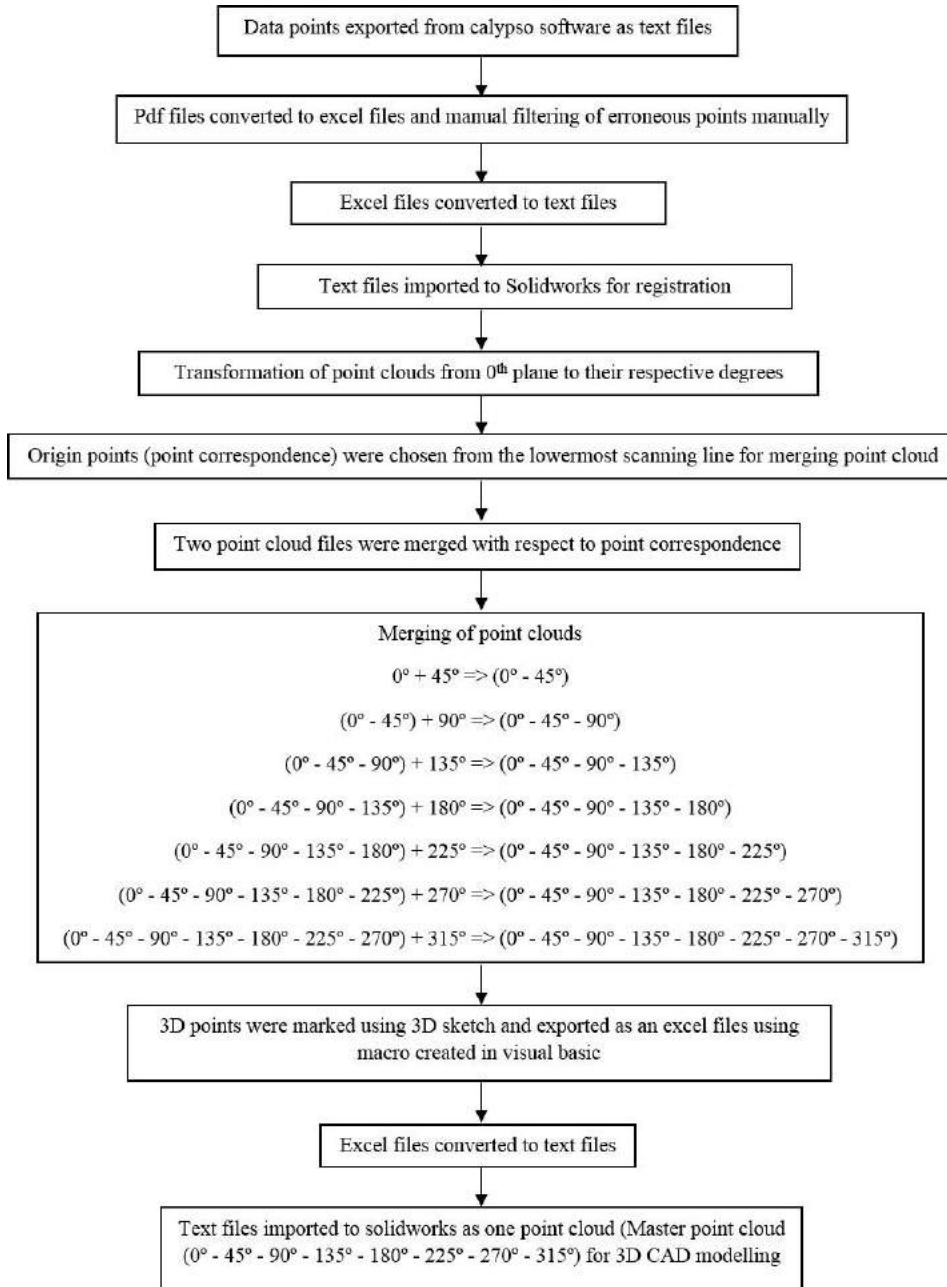


Figure 9: Preprocessing and registration of point cloud data.

Likewise, for 45° point cloud, with respect to origin point all other points were 3D marked and exported as text files. So, for the chosen origin point, the co-ordinates of the points in both the point clouds were changed. The XYZ points of both the point clouds were saved as one text file which were

imported to CAD software as one-point cloud for further processing as shown in Fig. 10(a). The point correspondence between 45° and 90° were used for merging ($0^\circ - 45^\circ$) and 90° . Likewise, remaining point clouds were merged to previous point cloud with respect to point correspondence and exported as one text file (master point cloud) as shown in Fig. 10 (b-g). This text file contains the master point cloud which has all the data points oriented to their respective co-ordinates for further CAD modelling.

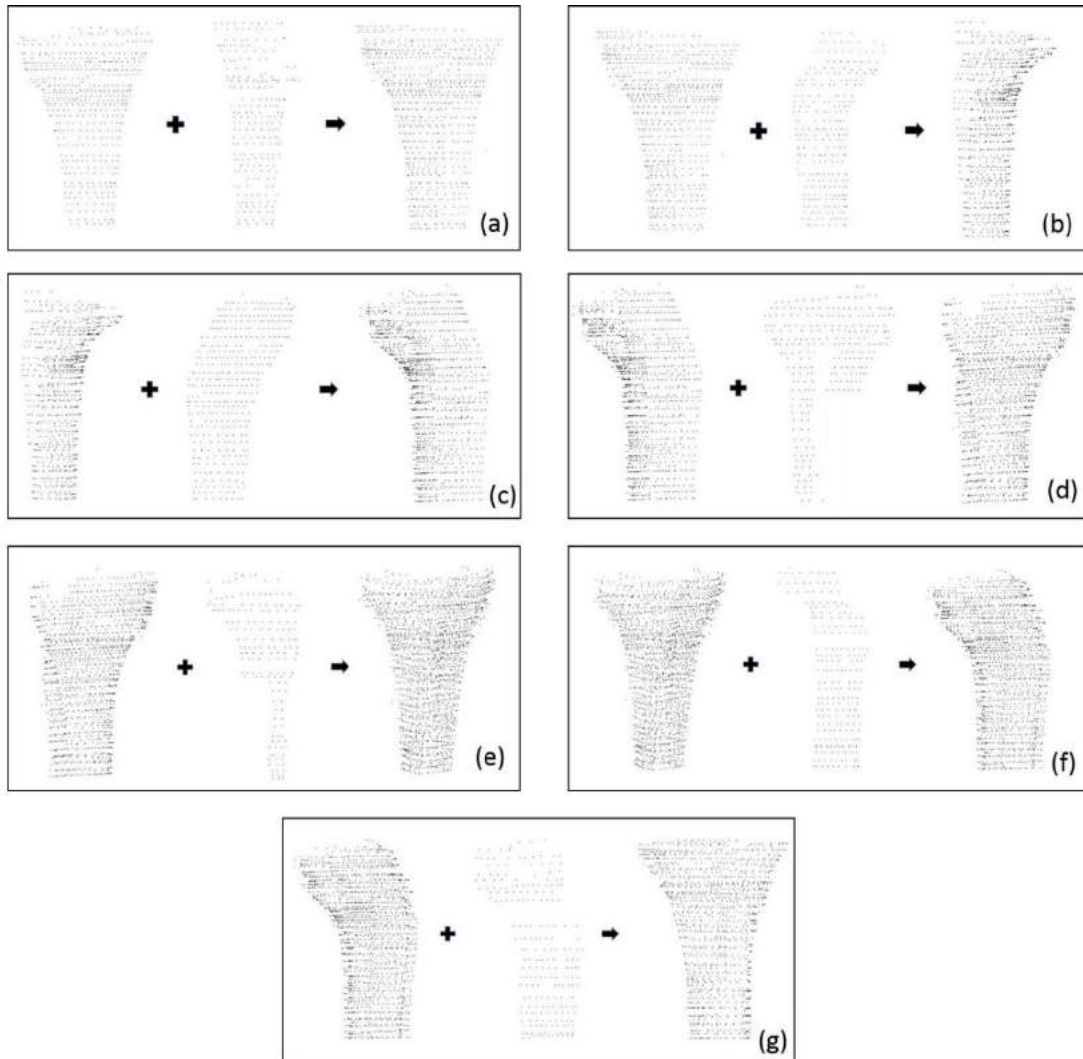


Figure 10: Merging of point cloud using point correspondence: (a) $0^\circ \times 45^\circ \Rightarrow (0^\circ - 45^\circ)$, (b) $(0^\circ - 45^\circ) \times 90^\circ \Rightarrow (0^\circ - 45^\circ - 90^\circ)$, (c) $(0^\circ - 45^\circ - 90^\circ) \times 135^\circ \Rightarrow (0^\circ - 45^\circ - 90^\circ - 135^\circ)$, (d) $(0^\circ - 45^\circ - 90^\circ - 135^\circ) \times 180^\circ \Rightarrow (0^\circ - 45^\circ - 90^\circ - 135^\circ - 180^\circ)$, (e) $(0^\circ - 45^\circ - 90^\circ - 135^\circ - 180^\circ) \times 225^\circ \Rightarrow (0^\circ - 45^\circ - 90^\circ - 135^\circ - 180^\circ - 225^\circ)$, (f) $(0^\circ - 45^\circ - 90^\circ - 135^\circ - 180^\circ - 225^\circ) \times 270^\circ \Rightarrow (0^\circ - 45^\circ - 90^\circ - 135^\circ - 180^\circ - 225^\circ - 270^\circ)$, and (g) $(0^\circ - 45^\circ - 90^\circ - 135^\circ - 180^\circ - 225^\circ - 270^\circ) \times 315^\circ \Rightarrow$ Master point cloud $(0^\circ - 45^\circ - 90^\circ - 135^\circ - 180^\circ - 225^\circ - 270^\circ - 315^\circ)$.

5.2.2 Generation of a 3D CAD model of a tibia bone

The master point cloud which was obtained after preprocessing and registration from the raw data was imported to Solidworks. The mesh preparation wizard and surface wizard of Solidworks was used for the generation of the 3D CAD modelling. The flowchart of the entire process is shown in Fig. 11. As all the points were oriented accordingly during preprocessing, there was no need for any orientation in this wizard. Noise removal was done as some points were error points and those points were mismatched from the entire point cloud. Those points were deleted by selecting rectangular and circular selections. Smoothing was done to remove the sharp edges of the model and to smoothen it. Lot of holes were there after smoothing, those holes were selected and patches were done. Surface wizard was used to generate the surface model from the mesh. All the surfaces were selected and knitted using knit feature. Extra points and regions were trimmed using trim feature to render the 3D CAD model. The modelling steps is shown in Fig. 12. The holes which were not filled using Solidworks fill option were repaired using meshlab software [2]. The Close hole option under remeshing tool was used to repair the 3D CAD model. Threshold with respect to hole size was fixed for repairing holes. The complete 3D CAD model of the tibia bone is shown in Fig. 13.

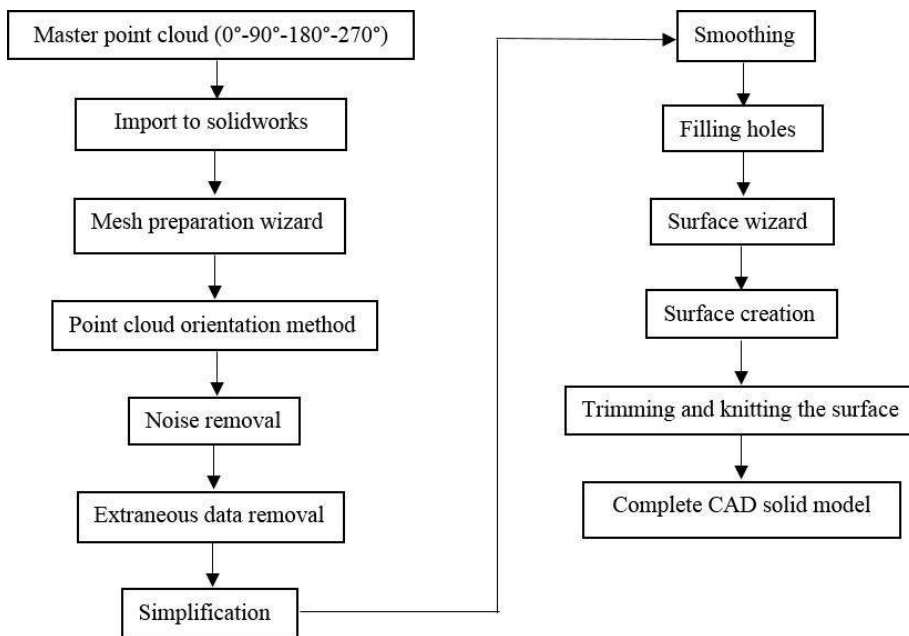


Figure 11: Flowchart for the generation of the 3D CAD model of tibia bone.

5.3 Comparative Analysis (Error Analysis) and Deviation Analysis

Deviation between master point cloud data and generated 3D CAD model was analyzed using cloudcompare software. The final model was compared with point cloud data using cloud/mesh distance tool. The colour gradient (Red, Green, Blue -RGB) was used to differentiate from zero deviation to maximum deviation as shown in Fig. 14. The blue region gives the zero deviation. The green regions are having minimum deviations. The red region gives the significant ones. The maximum error was found to be 0.314274 mm. Deviation analysis was also done using Autodesk Netfabb which has given the tolerance value of 0.0001 mm. Errors are due to the setting of fixtures, feature form errors that is because of deviation from defined geometries, fitting algorithms, dynamic errors (probe movement) and systematic errors.

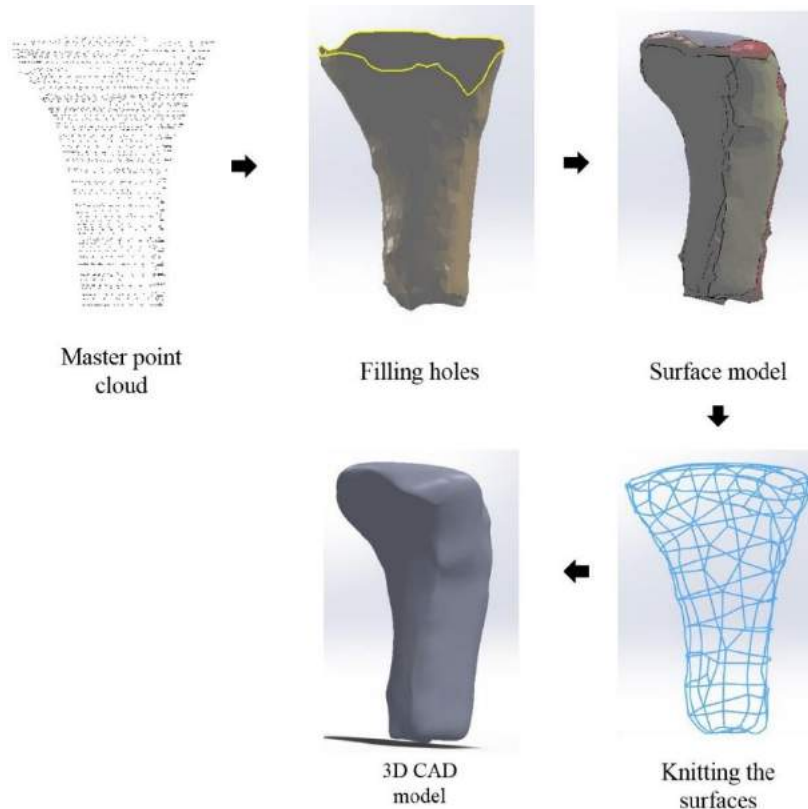


Figure 12: Steps in generation of the 3D CAD model of the tibia bone.



Figure 13: Complete model after repair using Meshlab.

Lin et al., have used the reverse engineering for 3D modelling of artificial joint using CMM. The deviation between point cloud and final model has given the maximum error value of 0.451 and tolerance value of 0.25 mm [10].

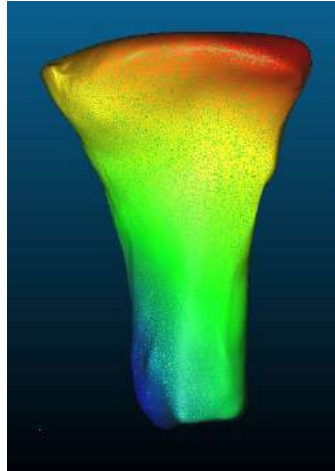


Figure 14: Comparison between point cloud and the final CAD model using Cloudcompare software.

The 3D models were compared by measuring some of the features of the tibia. The features such as tibial maximum proximal epiphyseal breadth, tibial maximum shaft diameter at nutrient foremen, tibial mediolateral shaft diameter at nutrient foremen and tibia circumference at nutrient foremen in the original phantom model were measured using Vernier caliper and flexible cloth tape. Tibia's circumference was measured for phantom model using flexible cloth tape. The other features in the phantom model were measured using Digital Vernier caliper. In CAD models, circumference was found by measuring radius at the foremen using 3-point arc method using the measurement tool in Autodesk Netfabb standard software. The other features in the CAD models also were measured using Netfabb. Measured data is shown in Tab. 2. The obtained measured values using Netfabb were close to the Vernier caliper and cloth tape measurement value.

Features in the tibia	Original model (phantom) (mm)	Obtained 3D CAD model (mm)	Error
Tibial maximum proximal epiphyseal breadth	61.48	60.5	0.98
Tibial maximum shaft diameter at nutrient foremen	23.22	23.814	0.594
Tibial mediolateral shaft diameter at nutrient foremen	27.25	27.396	0.146
Tibia circumference at nutrient foremen	94	94.787	0.787

Table 2: Comparative analysis of the generated CAD model with original phantom model of a tibia.

6 CONCLUSIONS

Complex-shaped object measurement was done using CMM with AM aided fixture box and 3D CAD model was generated using Solidworks. The components of the fixture box were designed using Solidworks and were printed using 3D printer. The parts of the fixture box were assembled inside acrylic box. Eight plane measurement of a tibia bone at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° were done using fixture box. Pre-processing and registration was done for all the point cloud. The point cloud obtained from each plane measurement were merged to obtain the final master point cloud. This master point cloud was used for the CAD modelling. CAD modelling was done using various tools in mesh preparation wizard and surface wizard and the 3D model was generated. The

generated model from Solidworks has some small patches and that was repaired using tools in meshlab software. The final obtained CAD model was compared with master point cloud for deviation analysis using cloudcompare and netfabb softwares. Comparative analysis between CAD model and original phantom model of the tibia bone was done. The features values in the CAD model was approximately equal to the feature values measured in original phantom model of the tibia bone. This CAD model can be effectively used for medical applications such as accurate implant modeling and pre-surgical planning.

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