A STUDY ON RETROGRADE FEMUR NAIL AND ITS GEOMETRIC MISMATCH IN INDIAN POPULATION.

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ABSTRACT

We studied 33 cases with distal femur or distal 1/3rd femur fracture treated with closed reduction and internal fixation using retrograde femoral nail for the geometric mismatch analysis of the retrograde nail. Based on a three-dimensional virtual model, we created using computed tomographic pictures a geometric model of the femur with retrograde nail in situ. Six levels were used for the experiment, which were at 130, 150, 170, 190, 210, and 230 mm measured from the condylar surface. Each level was evaluated according to the following criteria:

(1) intramedullary canal diameter;

(2) percentage of the unreamed intramedullary canal filled by the nail;

(3) minimum reamer diameter that required enlarging the canal to accommodate retrograde nail insertion;

(4) minimal inner cortical reaming thickness that needed to be removed.

(5) The proportion of the cortical bone surface that had to be ground down before the nail could be inserted;

(6) The distance between the centre of the intramedullary canal and the nail.

The majority of the studied models of the patient had a nail that was significantly mismatched, necessitating substantial reaming of the intramedullary canal to provide room for the nail implantation. A substantial likelihood of clinical problems could result from this. For use in the Indian population, the retrograde nail should be redesigned to be the right size and shape.

INTRODUCTION

It is now generally understood that the treatment for supracondylar fractures and distal femoral shaft fractures involves closed reduction internal fixation using intramedullary nailing using a retrograde nail inserted from distal to proximal from the intercondylar notch in the intramedullary canal [7, 8, 12–17, 19, 20]. When we used this modality of treatment in our patients it was found that we had to ream sequentially significantly indicating that there could be a possible mismatch in the anatomy of the Indian femurs and the retrograde nail design. The mismatch of the nail to the femur has been implicated in numerous reports of problems associated with intramedullary nail use [2, 5, 7, 10, 11].

These include inadequate anatomical alignment, subsequent fractures caused by bursting intramedullary nails to cortical bones, and bone deterioration as a result of extensive cortical reaming. Majority of the intramedullary nails available in the market are made using the Caucasian femur anatomy as a guide, using those devices in an Indian population may result in surgical problems [11].

The Leung et al. carried out a study on the mismatch analysis of the trochanteric gamma nail to the Chinese femur.[9] using two-dimensional radiography data technique. The Egol et al. [4] studied the mismatch analysis of gamma nail to the femur from the collection of museums in the United States using a similar two-dimensional approach. As a result of computed tomography (CT) technology's potent capacity to create three-dimensional medical models, this benefit was utilised by Mahaisavariya et al. [11] and Chevalley et al. [3] by using the computer-aided design/computer-aided manufacturing (CAD/CAM) to make three dimensional models to access the misalignment of intramedullary nails and comparing it to various size of femur in their sample. These studies discuss and explain how cutting-edge technology can be used for a better design of proximal femoral intramedullary nails. We carried out this study to increase knowledge of the therapeutic application of such retrograde nailing technology in Indian patients postoperatively because there hasn't been any prior research on the mismatch of retrograde nail to femoral canal in Indian population.

Methodology

We started with initially going through the literature for any research and methodology for analysis of the mismatch of the nail and the bone. There was an inadequacy in the studies done on retrograde femur nail in the Indian population. Hence, we decide to analyze the nail design with respect to the anatomy of the Indian femur for any geometric mismatch. We decide to utilize reverse engineering, CAD/CAM, and CT imaging to create 3D models of the femur with nail in situ. The important aspects of geometric mismatch of nail design and femur anatomy could be accessed using a three dimensional model based research. In this study, all three-dimensional models of the femur and retrograde nail were created utilising reverse engineering methods (Phillips integrated CT Software)

Data acquisition

33 adult femora samples were studied from the radiology and orthopedic departments at the Dr. D. Y. Patil Hospital, Pimpri, Pune between January 2022 and September 2022. A CT scanner was used to scan each patient pre and postoperatively to obtain the original femur anatomy preoperatively which was later compared with the postoperative femur anatomy with the retrograde in situ. The data were captured at 2 mm slice thickness in the proximal and distal regions, and the interpolation was carried out at 1-mm slice thickness. The interpolation of the femoral shaft was carried out at 5mm, while the geometric data were captured at a slice thickness of 10 mm. A three-dimensional model of the femur was created utilizing the CT images collected from the CT scanner. The geometry of several femur areas was extracted using multiple threshold settings. The cortical region had the high threshold value and the intramedullary canal received the low threshold value.

The 260-mm-long retrograde nail with 10 mm diameter was used in this study (Yogeshwar Surgicals, INDIA). The retrograde nail's geometry was recorded using a three-dimensional laser scanner. Following is a summary -

1. Splitting the femoral area. Each femur was split into three areas, as shown in Fig. 1a. Femoral length is divided into two parts at 35 and 65% [18].

The proximal femur is located above the 35% border line. The femoral shaft is the area between the 35 and 65% border line. The distal femur occupies the space below the 65% boundary line.

2. The femoral shaft axis calculation. The intramedullary canal in the femoral shaft region provided the femoral shaft axis, as shown in Fig. 1b. We used the preoperative CT scan axial cuts to make two dimensional circles corresponding to the intramedullary canal's cross section. Then we used these two-dimensional intramedullary canals to make the femoral shaft axis by aligning them using the linear regression technique

3. The Retrograde nail axis. The retrograde nail axis was determined based on the exterior of the retrograde nail in the straight region, as shown in Fig. 1c. We simulated the retrograde nail's surface as a two-dimensional circle and determined the retrograde nail axis by aligning the centers of each circle using a linear regression technique.

4 4. Aligning the retrograde nail's axis with the femoral shaft's axis As seen in Fig. 1d, the retrograde nail axis was matched with the femoral shaft axis utilizing CAD software's "Best-fit alignment" features. It is a function that aligns the objects using the axis of each one as a reference. The retrograde nail was only permitted to rotate and translate along the femoral shaft axis once the two axes had crossed over. When the distal screw of the retrograde nail was parallel to the anteroposterior axis, the retrograde nail was twisted. Until the distal end of the retrograde nail was situated just below the cortical condylar surface, translation along the femoral axis was repeated.

As illustrated in Fig. 2, the geometric mismatch parameters were assessed. These included the intramedullary canal's diameter, the percentage of the cortical bone that needed to be removed before the nail was inserted, the minimal reamer diameter that required enlarging the canal to accommodate retrograde nail insertion, the minimal inner cortical reaming thickness that was necessary, and the deviation of the nail's centre from the cortical bone's centre. Investigations were conducted at six levels that were 130, 150, 170, 190, 210, and 230 mm above the condylar surface.

The assessment's specifics can be summed up as follows:

1. Fitting circle – The two-dimensional circular approximation approach was utilised to approximate the intramedullary canal and retrograde nail diameters at each consideration level. At this stage, the intramedullary canal's unreamed diameter may be measured.

2. calculating the parameters for geometric mismatch. The following formulae [11] were used to derive the additional geometric mismatch parameters.

2.1 The portion of the unreamed intramedullary canal that the nail fills.

$\%\text{area filled in the canal} = \%\ (\text{area}^{\text{filled by nail}} / \text{area}^{\text{canal}})$

2.2 The minimal reamer diameter that is required to ream in order to accommodate the nail in the femoral canal

$\text{Minimal reaming diameter} = 2 \times (\text{radius}_{\text{canal}} + \text{distance}_{\text{out of centricity}})$

2.3 The minimal inner cortical reaming thickness that requires removal for an optimal implant placement.

$\text{minimal inner cortical reaming thickness} = (\text{minimal reaming diameter} - \text{canal diameter}) / 2$

2.4 The percentage of the cortical bone area that needed to be removed prior to nail insertion.

$\%\text{bone removal} = \%(\text{area}^{\text{minimal reaming}} - \text{area}^{\text{canal}}) / \text{area}^{\text{canal}}$.

2.5 The deviation of the nail center from the center of the intramedullary canal

$\text{The deviation of the nail center from center of the canal} = \text{position}_{\text{canal center}} - \text{position}_{\text{nail center}}$

Results

This study found that the results could be divided into two groups based on the geometric mismatch feature. The specimens for Group A showed substantial mismatch, as shown in Fig. 4, showing that the retrograde nail is displaced significantly from the outer cortical margin. In Group B, there was no significant mismatch in the specimens that would have allowed the retrograde nail to fit inside the femur's outer cortical limit. Only 5 femurs were in Group B, according to insertion, which shows that 28 femora (or 87%) were in Group A. The average geometric mismatch characteristics of 3 adult femora at each level were then assessed since the key aspect occurred in Group A, as shown in Table 1.

Discussion

The development of three-dimensional medical models is made possible by advancements in a variety of technical technologies, including reverse engineering and the CT scanner. This makes it possible to examine the intricate geometric structure, which would be challenging to do with a traditional two-dimensional radiography technique. Additionally, it enables access to the internal geometry of bone, particularly the intramedullary canal. There are two papers that have assessed the mismatch of the nail to the proximal femur using CT technologies [3, 11]. To our knowledge, there has never been a study on the geometric mismatch analysis of the retrograde nail to the femur. Based on three-dimensional models, this study evaluated the geometric misfit characteristics between the femur and the retrograde nail. According to the analysis, using a more appropriate retrograde nail in an Indian femur is crucial. The majority of the specimens showed substantial mismatches, which the retrograde nail's radius of curvature could not make up for in relation to the intramedullary canal's radius of curvature.

The ideal nail design should be made taking in consideration the mid-shaft femur rather than the distal femur regardless of the fact that this study's focus was on the retrograde nail system. This is due to the bone's tiny size in the mid-shaft region and the lack of available room for accommodating nails. In order for the nail fixation to be stable, the nail must be positioned with appropriate distance within this femoral shaft region. The mismatch analysis of the distal section can be validated after the mismatch at the shaft region was examined.

In contrast to the Indian femur, which revealed large degrees of curvature, thel retrograde nail's shaft part is typically very straight [1]. It has been discovered that the curvature of the Indian femur is greater than that of the caucasian population.

Therefore, the suitable length of the retrograde nail must be taken into account in order to prevent nail penetration or impingement on the anterior cortex depending on caucasian design. It is advised that the nail length be adequate to cover the supracondylar fracture. As a result, it is possible to accommodate nails without having to compromise the architecture of the mid-shaft, and undue reaming across the fracture site need not be done. However the use of a retrograde nail when used in a mid-shaft femur fracture will require certain amount of over-reaming in order to accommodate the nail which is straight as against the curved femur. At this stage we

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should also take into account that there is a reduction in bone strength associated with over-reaming. [6].

We can attempt manipulation at the fracture site to restore the femur curvature while inserting the nail but it may not resemble the original curvature. Therefore, redesign is advised to achieve the proper femoral curvature and to reduce any difficulties from employing the current retrograde nail. An appropriate nail design will be obtained taking in consideration the morphometric data of the intramedullary canal, the femoral radius of curvature, and geometric mismatch data analysis. The ideal retrograde nail diameter for Indian populations is around 10 mm. The radius of curvature of the existing retrograde nail should be lowered to about 900 mm, which appears to be the main alteration [1]. Further research on the new design's biomechanical performance evaluation is also necessary.

We were able to realistically investigate the geometric mismatch parameter in three dimensions thanks to a variety of modern virtual prototyping technologies, including reverse engineering, CAD/CAM, and medical image processing. Before these technologies were developed the evaluation of geometric mismatch was using a two -dimensional technique or manual measurements which were less accurate and high chance of false data because of limitation in assessment and human error of measurement.

This study methodology of using a three dimentional approach to assess the geometric adequacy and mismatch analysis can be of help to study different methods of fracture fixation as well. A surgeon would benefit from knowing the potential risks associated with using the current intramedullary fracture fixation design in a particular population through this type of investigation. Additionally, it would be beneficial to redesign devices in accordance with geometric mismatch parameters to minimise any potential implant-related complications.

Conclusion –

Summarizing the study, we demonstrated a cutting-edge method for evaluation of the geometric adequacy of the nail design when compared to the anatomy of the femur bone using CT data from preoperative and postoperative patients. Our ability to create three-dimensional CAD models of the femur and implant is considerably enhanced by technologies like medical image processing, CAD/CAM and reverse engineering. The evaluation of geometry in three-dimensional configurations as against the normal two-dimensional radiography techniques which cannot access as accurately, is another outstanding characteristic of application of these cutting-edge technologies. Using this method, it was possible to get numerous relevant points on the geometric mismatch of the retrograde nail in the Indian femur. The data clearly reveal that the retrograde nail's current design is significantly out of proportion to Indian femurs. It is strongly advised that the retrograde nail be redesigned for the Indian population.

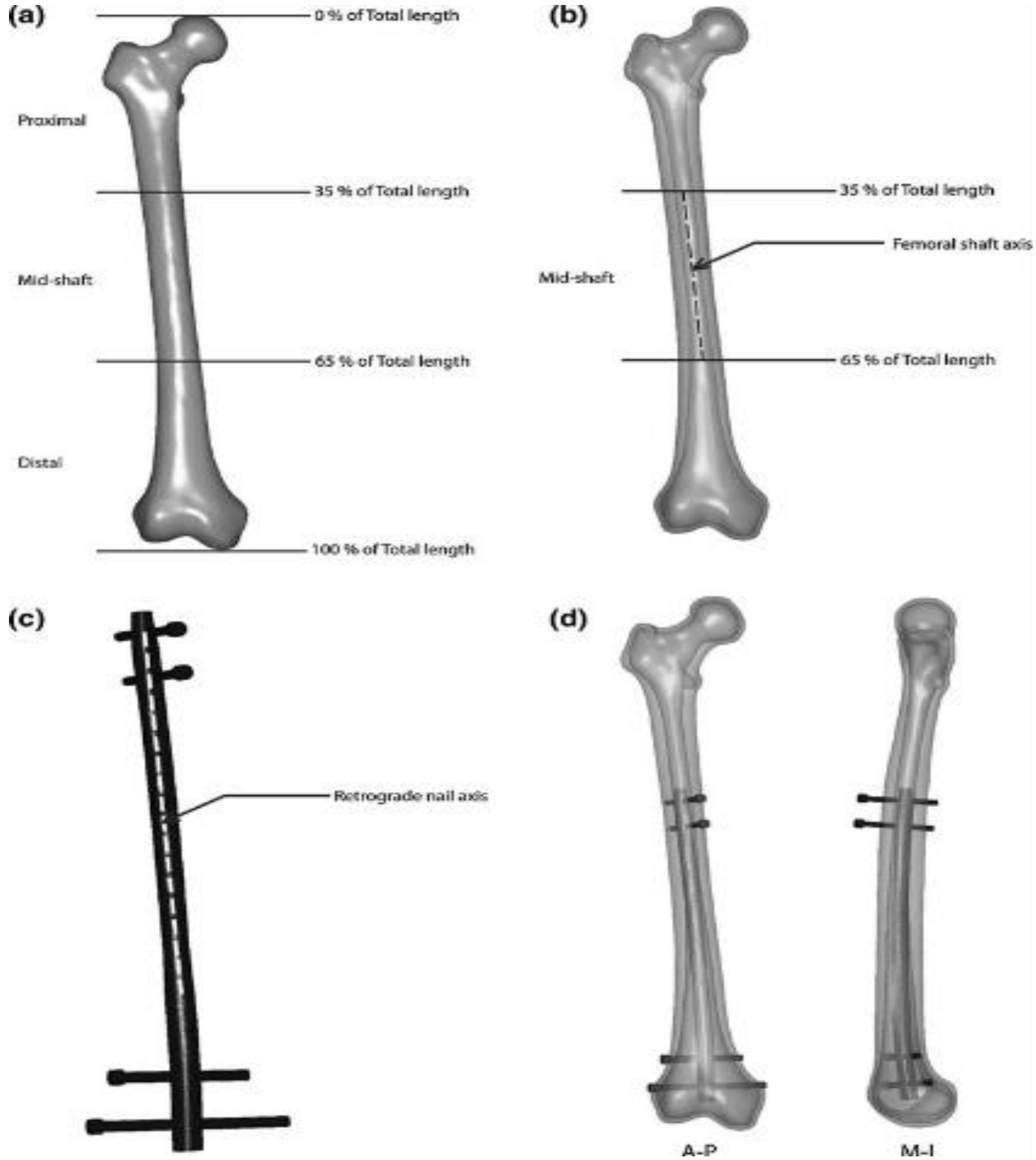

Fig. 1 The insertion of retrograde nail into the femur

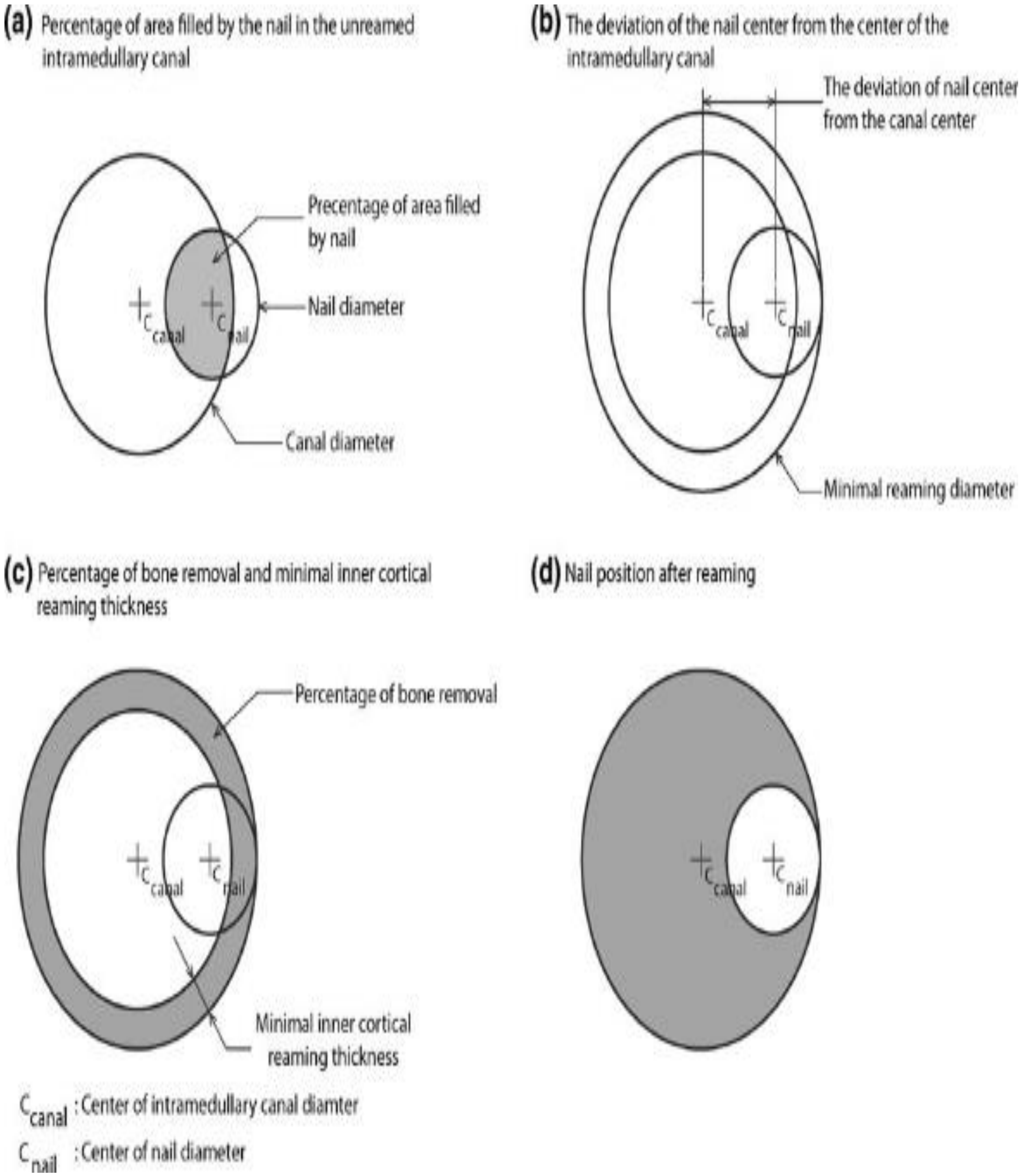

Fig. 2 The parameters used for geometric mismatch calculation

	D130	D150	D170	D190	D210	D230
DIAMETER OF INTRAMEDULLARY CANAL	16.3 ± 3.2	14.5 ± 2.9	13.1 ± 2.7	12.1 ± 2.4	11.5 ± 2.2	11.2 ± 2.1
Area filled by nail in %	53.8 ± 29.0	59.5 ± 24.5	70.5 ± 20	80.4 ± 14.3	94.4 ± 8.3	95.2 ± 5.7
Minimal reamer diameter	18.4 ± 2.1	16.2 ± 1.6	14.4 1.1	12.7 ± 0.8	11.4 ± 0.6	11.1 ± 1.0
Minimal cortical reaming	1.1 ± 1.0	1.0 ± 0.8	0.9 ± 0.9	0.5 ± 0.8	0.4 ± 0.8	0.5 ± 0.9
Cortical bone removal %	38.8 ± 43.5	38.5 ± 47.4	35.1 ± 49.9	29.0 ± 54.3	25.9 ± 67.0	50.1 ± 85.3
Deviation of nail from centre	4.2 ± 1.1	3.3 ± 0.7	2.3 ± 0.6	1.5 ± 0.4	0.8 ± 0.3	0.9 ± 0.6

Conflict of interest There are no benefits directly or indirectly in any form whatsoever received or in process from any commercial enterprise in regards of this study or article.

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