INTRODUCTION:

Percutaneous osseointegrated implants as a docking technology for exoprosthesis limbs are being considered around the world as alternatives for sockets. Morphometric variations of the periosteal surface of long bones have been identified [1]. Until the recent interest in percutaneous osseointegrated implants, which use the intramedullary canal for fixation, no data were available to quantify the variance of femoral curvature in the sagittal plane based on age, gender and ethnicity (AGE). These data are critical for establishing implant design parameters that are required to assure endosteal attachment of these percutaneous osseointegrated implants. The purpose of this investigation is to determine if there are any morphological differences in the sagittal femoral bow and break point based on age, gender and ethnicity.

METHODS:

A total of 178 cadaveric femurs from donors of varying AGE were obtained (Table 1).

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Age [years]</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>African American</td>
<td>44.5 ± 4.0</td>
<td>48</td>
<td>15</td>
<td>63</td>
</tr>
<tr>
<td>Caucasian</td>
<td>34.3 ± 2.4</td>
<td>70</td>
<td>27</td>
<td>97</td>
</tr>
<tr>
<td>Hispanic American</td>
<td>32.6 ± 3.7</td>
<td>18</td>
<td>0</td>
<td>18</td>
</tr>
<tr>
<td>Total</td>
<td>37.7 ± 2.1</td>
<td>136</td>
<td>42</td>
<td>178</td>
</tr>
</tbody>
</table>

Each femur was placed into anatomical position and CT images were taken with a GE High Speed CTI single slice helical scanner every 1 mm along the entire length of each bone at a pitch of 1 (1x1x1), MAS=100, and kV=100, FOV (field of view)=16cm. 3D reconstructions of the cortical bone and femoral canal were made using commercially available software, (MIMICS, Materialize, USA). Center of area data for the medullary canal of each femur were calculated for each slice along the region from 35-80% of the biomechanical length (BML) [2].

The method for determining the bow was consistent with a previous study [3]. The point along the femur at which the angle was measured was determined by calculating the break point of two lines using a statistical method to minimize the residual sum of square [4]. Two line segments were defined using linear approximation from 35% BML to the calculated break point and then from the calculated break point to 80% BML. The acute angle between the defined lines was calculated using a custom Matlab program (Mathworks, USA) and taken to represent the angle of incidence of the femoral bow (Figure 1).

![Figure 1 – Image of a reconstructed femur showing the method of calculating the bow and break point.](image-url)

The resultant bow and break point data were separated by AGE. Age was separated into four groups: 15-25, 26-35, 36-45 and 46-72 years old. Statistical significance between AGE was defined as a p-value of less than 0.05 from a multivariable mixed-effects linear regression model.

RESULTS:

Experimentally the average angle of incidence of the femoral bow was found to be 7.08 ± 0.19º for the 178 bones. The break point of the femoral bow was found to be at 59.3 ± 0.37% of the BML or 26.2 ± 0.32 cm from the distal end of the femur. For African Americans, Caucasians and Hispanics the break point occurred at 27.0 ± 0.64 cm, 25.9 ± 0.33 cm and 25.4 ± 1.00 cm respectively from the distal end of the femur.

There was no statistically significant difference in the femoral bow in the sagittal plane based on gender with a p-value of 0.80 and a percent difference of 0.24%. Age also showed no statistically significant difference for the break point of the femoral bow with p-values ranging from 0.08 for the comparison between 36-45 year olds and 46-72 year olds to 0.65 for the comparison between 15-25 year olds and 26-35 year olds. Percent differences for age ranged from 0.53% for the comparison between 15-25 year olds and 26-35 year olds to 1.97% for the comparison between 36-45 year olds and 46-72 year olds. Statistically significant difference based on ethnicity was found in the comparison of African Americans to Hispanics with a p-value of 0.01 and a percent difference of 13.1%. All other group comparisons had p-values greater than 0.13 and a percent difference of less than 8.96%.

DISCUSSION:

The femoral bow in the sagittal plane and break point are important characteristics to quantify for the development and design of osseointegrated implants. Knowing the location of the break point is especially important when dealing with straight intramedullary osseointegrated implants. Modeling the femoral canal as two line segments subtended by a small angle of incidence simplifies the design of intramedullary femoral implants. This allows implants to remain straight instead of requiring a curvature to them. Only at the break point of the femur would the implant need to be curved. Therefore, only in the region surrounding the break point is it important to know the sagittal bow angle.

For example given a 10 cm long implant and using the average location of the break point for all bones sampled, amputation could be performed up to 16.2 cm from the distal end of the femur before a curved implant would be needed. Once the amputation level becomes greater than 26.2 cm from the distal end of the femur a straight implant should be used instead of a curved one. It is therefore concluded based on current straight implant designs that knowing where the break point lies along the femur, and not the femoral bow, is the most important characteristic in the design and development of intramedullary osseointegrated implants.

Statistically significant difference was only found in the break point data based on ethnicity. This suggests that ethnicity may be a more important variable to consider in the design and development of femoral intramedullary implants than are age and gender.

REFERENCES:


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