**Testing Protocol**

The purpose of the testing protocol is to see if the desired range of motion is achieved with the rotation-rotation-rotation joint configuration design within the specified requirements. In order to complete Unicompartmental Knee Replacement Surgery the tool must have access to both femoral lobes. This can be achieved in two ways; (1) a linkage mechanism with a range of approximately 16 cm - equivalent to the entire knee - or (2) a linkage mechanism in which linkage 3 is adjustable to allow operation on individual lobes using the same mounting position.

**Max range/volume**

This test is to determine the ideal length of linkage 4 in two situations; (1) to access the entire knee from one position, and (2) to access individual lobes.

Assumptions/Requirements:

1. Device is fixed to femur (no play in the bone mount)
2. Angle between link 1 and link 2 is maximum 135 degree
3. Link 2 can never be perpendicular to the generated surface
4. Link 4 has a maximum angle of 45 degrees from the vertical position
5. Link 4 cannot come into contact with the support structure
6. Tool must have a 2 cm vertical range
7. Entire knee envelope has a radius of 8cm
8. Single lobe envelope must be 16cm by 8cm
9. Lateral deflection cannot occur

Setup:

|  |  |  |  |
| --- | --- | --- | --- |
| Setup Number | Link 3 Length [cm] | Link 4 Length [cm] | TKR or Unicompartmental |
| 1 | 8 | 12 | TKR |
| 2 | 8 | 11 | TKR |
| 3 | 8 | 10 | TKR |
| 4 | 8 | 9 | TKR |
| 5 | 8 | 8 | TKR |
| 6 | 8 | 7 | TKR |
| 7 | 8 | 6 | Uni |
| 8 | 8 | 5 | Uni |
| 9 | 8 | 4 | Uni |
| 10 | 8 | 3 | Uni |
| 11 | 8 | 2 | Uni |
| 12 | 8 | 1 | Uni |

Method:

1. Set reference point where link 4 is perpendicular to surface - this corresponds to the point at center of femur
2. Position envelope box centre at reference point
3. Position tool (end of link 4) at a corner of the envelope
4. Measure the angles of the linkages at each of the joints
5. Repeat for all 8 positions
6. Repeat for all setups

Questions:

* Is the workable area sufficient?
* Are there any areas where the tool cannot be oriented?
* Note: max range should be before lateral deflection occurs (when link1 is almost 90 degrees)

Results:

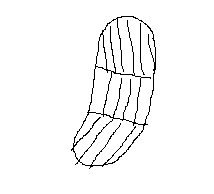
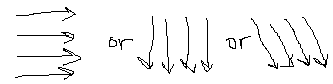
|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Setup | Link 4 Length [cm] | Link 1 Angle [deg] | Link 2 Angle [deg] | Fulfill pos requirements? | Fulfill angle requirements? | Lateral deflection? |
| 1 |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |
| 4 |  |  |  |  |  |  |
| 5 |  |  |  |  |  |  |
| 6 |  |  |  |  |  |  |
| 7 |  |  |  |  |  |  |
| 8 |  |  |  |  |  |  |
| 9 |  |  |  |  |  |  |
| 10 |  |  |  |  |  |  |
| 11 |  |  |  |  |  |  |
| 12 |  |  |  |  |  |  |

**Future Steps: Implant Shape**

This test is to determine if the device is able to orient and maneuver in the implant shape.

Assumptions: device is fixed to (perhaps pre-cut?) femur.

1. While keep the “cutting bit” perpendicular to the cutting surface, trace these shapes with various stroke directions



1. Repeat for the other condyle with current mount point if possible.

* Are there any issues with maneuverability?
* Are there any inaccessible regions?

**Angular error/surface penetration**

This test is to determine how much “bending” there is when the device is rigid.

Assumptions: device has all points fixed in a position where the hard constraint is active and max error could occur

1. Apply a reasonable and uniform force (???) into the “surface” and record any error observed.

* Error should be less than 3 degrees or less than 1mm of surface penetration