The information contained in this document is intended for healthcare professionals only.
The Duracon® Knee Design Rationale

Tibiofemoral Articulation
The Duracon® System includes several styles of femoral components, tibial inserts, and an all-polyethylene tibial implant. All of these components share the same basic tibiofemoral articulation design goals. The worldwide clinical experience with this knee in hundreds of thousands of cases since 1991 demonstrates the effectiveness of the Duracon® Knee articular surfaces.
INTRODUCTION

Perhaps the single most important feature of a total knee design is the tibiofemoral articulation. This design aspect has direct implications for the immediate and long-term success of the total knee components. Articular surfaces define the legitimacy of a total knee system’s clinical results. Since 1991, the tibiofemoral articulation of the Duracon® knee has remained absolutely unchanged.

The tibiofemoral articulation of the Duracon® Knee balances the need for conformity and the resultant reduction of contact stresses with the natural kinematics and the realities of total knee surgery.

Conformity and Stress Reduction

The Duracon® Knee:
- Maintains substantial contact area throughout the range of motion.
- Limits contact stresses even in conditions of varus/valgus misalignment.
- Provides generous UHMWPE thickness.

Natural Kinematics and TKA Realities

The Duracon® Knee:
- Accommodates physiological internal/external rotation.
- Includes designs that resist subluxation when the PCL is sacrificed or compromised, a common surgical occurrence.
- Allows for tibiofemoral sizing mismatches to meet the anatomic realities of TKA.

Since 1991, critical interplay between design, kinematics, and clinical performance of the Duracon® Knee has produced a system of implants to successfully treat the total knee patient. The ensuing pages present the research and development work behind the tibiofemoral articulation of the Duracon® Knee, and other useful information about this design.
A key design criterion in the development of the Duracon® Total Knee System is the maintenance of large areas of contact throughout the range of motion of the knee. Some total knee implants have been designed to have large areas of contact in the 0° to 15° range of flexion. While high stresses occur between 0° to 15° of flexion during walking, high tibiofemoral loading also occurs during many other normal daily activities. During activities such as rising from a chair and ascending and descending stairs, the knee can experience loads ranging from three (3) to seven (7) times body weight. During these normal activities, the knee is flexed at angles much greater than 15°, and can internally/externally rotate ±17°.

Table 1 indicates the flexion orientation of the knee, internal/external rotation, and the functional loads carried by the knee during several activities as shown in a review of the literature. From the Table, it can be seen that substantial peak forces are reached with many daily living activities. Therefore, it is important that contact area be maintained over all anatomically relevant degrees of flexion and internal/external rotation.

**Table 1**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Flexion Angle (°)</th>
<th>Tibial Rotation Angle (°)</th>
<th>Peak Force (Body Weight)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walking¹</td>
<td>15</td>
<td>0-5</td>
<td>3</td>
</tr>
<tr>
<td>Walking²</td>
<td></td>
<td></td>
<td>3.5</td>
</tr>
<tr>
<td>Descending Stairs¹</td>
<td>60</td>
<td>17</td>
<td>3.8</td>
</tr>
<tr>
<td>Ascending Stairs¹</td>
<td>45</td>
<td>14</td>
<td>4.3</td>
</tr>
<tr>
<td>Rising from chair³</td>
<td>90+</td>
<td>*</td>
<td>3 to 7</td>
</tr>
<tr>
<td>Squatting⁴</td>
<td>140</td>
<td>*</td>
<td>5 to 5.6</td>
</tr>
</tbody>
</table>

* No reference available

Table 1: This table illustrates the high forces present throughout ROM of a human knee.
Laboratory bench-top measurements of contact areas of prosthetic components are used to investigate and confirm total knee design criteria. Bench-top testing has the advantage of allowing contact area to be measured easily without introducing uncontrollable variables associated with human cadaveric specimens, such as bone geometry/properties and surgical technique variation. Care must be taken, however, to see that the pertinent conditions determining tibiofemoral contact are recreated in the laboratory. Most recent reports of contact area have been performed with the components in neutral rotation. Physiological rotational orientation is generally not taken into account. Howmedica Osteonics’ Research & Development biomechanical testing laboratory conducted testing in which internal/external rotation was introduced to an amount expected during clinical use. In this test, contact area differences of greater than 15% have been measured compared to the contact areas measured in neutral rotation.5

The design goal of the Duracon® Knee tibiofemoral articulation was to maximize contact throughout the range of motion. Contact area measurements were made on the condylar and A/P lipped components. Several competitive designs were also tested. The testing was performed at physiological flexion and internal/external orientations following the literature references compiled in Table 1. All contact area measurements were made with the use of Fuji Film.6 All testing was done at a 667N (150lb) load level. Figure 1 shows the test setup. The resulting medial and lateral contact areas were summed at each angle of flexion/degrees of rotation.

Figure 1
Contact area test setup used to compare the Duracon® Knee contact area with other designs.
This testing clearly demonstrates the two main design philosophies in tibiofemoral articulation apparent among the various manufacturers. The first approach is seen in the Genesis® design. This system appears to have focused concern for contact area to the lower degrees of flexion only. The components have been designed to have large areas of contact in the 0° to 15° range of flexion, but show dramatic decreases in contact area at higher angles of flexion. The Genesis® design has a larger area of contact than the Duracon® Knee components at 0° of flexion, similar areas of contact at 15° to 30° of flexion, and significantly smaller areas of contact at 45° to 90° of flexion. In contrast to the Genesis® design, the Duracon® Knee implants maintain substantial levels of constant contact area over the flexion angles tested.

The second tibiofemoral design philosophy is demonstrated by the Duracon® Knee and AMK® Systems. This approach maintains contact throughout the range of motion. There is, however, one very significant difference between the Duracon® knee and AMK® articular surfaces contact. On average, the Duracon® Knee System has a 25% larger area of contact than the AMK® System. The goal of the Duracon® Knee design is not merely to have consistent contact, it is to have **large areas** of contact **throughout** the range of motion.

It has been demonstrated that peak loads for the knee for normal activities occur at angles of flexion greater than 15°. In these tests, it was demonstrated that competitive devices pursued one of two design philosophies, showing either a significant decrease in contact areas as flexion was increased or simply maintaining low contact areas in various degrees of flexion. In contrast, the Duracon® Knee System has a tibiofemoral articulation that maintains high levels of contact area throughout the range of motion. The high degree of conformity demonstrated by the Duracon® Knee components throughout the range of motion leads to reduced contact stresses and offers the opportunity for enhanced long-term component durability.

Figure 2a & 2b: Results of contact area studies. Total contact area is the sum of contact areas measured on medial and lateral condyles.
**Contact Area Results (The Duracon® Knee vs. Genesis®)**

![Bar Chart: Contact Area Results (The Duracon® Knee vs. Genesis®)](chart1.png)

Figure 2a: Genesis® has only one test point where its contact area is notably higher than the Duracon® Knee. In higher degrees of flexion, the Duracon® Knee has greater contact area.

**Contact Area Results (The Duracon® Knee vs. AMK® System)**

![Bar Chart: Contact Area Results (The Duracon® Knee vs. AMK® System)](chart2.png)

Figure 2b: AMK® System has consistent contact area that is lower than that of the Duracon® Knee at all points of flexion.
Reducing Point Contact Even When Malalignment Occurs

The Duracon® Total Knee System femoral components have generously radiused distal condyles that conform to the radii of the tibial insert in the coronal plane. This increases the surface contact area and reduces contact stresses. Additionally, the broad radii on the edges of the femoral component prevent sharp edge contact, and ensure that large areas of contact are maintained if varus/valgus liftoff occurs (Figure 3).

A series of tests was performed to evaluate the effect of varus/valgus liftoff/malalignment of the Duracon® Tibial and Femoral Components on contact area and contact pressure. The tibial and femoral components were mounted as described in the previous section and as shown in Figure 1. The femoral component was tested in a 0° and a 3° varus orientation (Figure 3). Contact area and pressure measurements were made using a Tekscan Measurement System (Tekscan Inc., Boston, MA). Measurements were taken at 15°, 60°, and 90° of flexion. The ratio of the varus/valgus contact area to the neutral contact area and the ratio of the varus/valgus contact pressure to the neutral contact pressure were calculated to show the percent of change in contact area and contact pressure when a component is malaligned by 3°. Figures 4 and 5 show the results of the contact area and contact pressure measurements, respectively. Results of similar testing from the testing laboratories of J&J Orthopaedics on the PFC® Sigma components are included for comparison.7

Figure 1
Contact area test setup used to compare the Duracon® Knee contact area with other designs.
The geometry of the Duracon® Total Knee System is designed to maintain large areas of contact, even during liftoff. Broad radii at the articular margins of the femoral component reduce any potential of edge loading.
The results for the Duracon® Knee and J&J PFC® Sigma components show that contact areas are reduced on the order of 31% for both components when the components are oriented in 3° of valgus (Figure 4). More importantly, while the average contact area reduction is similar for both components (Figure 5), the Duracon® Total Knee System shows significantly lower increases in contact pressure when oriented in 3° of valgus. The Duracon® Inserts show an average of a 7% (maximum of 16%) increase in contact stresses, while the J&J PFC® Sigma components show an average of a 31% (maximum of 37%) increase. Increased stress has been identified as having a deleterious effect on polyethylene wear characteristics.

Even with the use of accurate knee alignment instrumentation, the complexities of TKA do not preclude the possibility of malaligned tibiofemoral articulating surfaces. Malalignment leads to increased stresses, which have been identified as a key factor in accelerated polyethylene wear. The broadly radiused distal condyles of the Duracon® Femoral Components ensure that large areas of contact are maintained even in 3° of malalignment. And more importantly, the contact stresses are only minimally affected. Thus, even in conditions of malalignment, the Duracon® Knee tibiofemoral articulation maintains the potential for the good wear properties demonstrated at perfect varus/valgus alignment.
Effect of Varus/Valgus Liftoff on Contact Area

![Graph showing normalized contact area comparison between Duracon and PFC components at various flexion angles.]

Varus/Valgus Liftoff Results on Contact Pressure

![Graph showing normalized contact pressure comparison between Duracon and PFC components at various flexion angles.]

This zone indicates the % increase in contact pressure of malaligned components versus a neutrally aligned component.

Figures 4 and 5:
Comparison of contact areas in neutral and 3° of valgus alignment for the Duracon® Knee and J&J PFC® Sigma components are presented in Figure 4. When malaligned 3°, the reduction in contact area is similar for both the Duracon® Knee and J&J PFC® Sigma. For example, both maintain approximately 70% of the contact area at 15° of flexion when malaligned.

Figure 5 illustrates contact pressure. The J&J PFC® Sigma shows a much greater increase in contact stresses than does the Duracon® Knee when components are malaligned. For example, at 60° of flexion, the Duracon® Knee has virtually the same contact pressure when malaligned as it does in neutral. For J&J PFC® Sigma there is an over 20% increase in contact pressure.
The Duracon® knee reduces contact stress through its articular conformity and a 6.2mm minimum polyethylene thickness.

Reducing Maximum Contact Stresses with Generous UHMWPE Thickness

In the late 1980s, several published studies implicated polyethylene thickness as a key factor in the stresses developed in the tibial insert of total knee arthroplasties. Bartel et al.9,10 published results concerning the effect of polyethylene thickness on contact and subsurface stresses of a Total Condylar-type prosthesis. This initial work demonstrated that contact and subsurface stresses for the implants tested were related to UHMWPE thickness.11 The authors’ general conclusion was that for metal-backed tibial component surfaces, plastic thickness should be greater than 6mm.

The Duracon® System acknowledges this work in the tibial component design. Duracon® inserts have a minimum thickness of 6.2mm. The graph in Figure 6a shows that the insert thickness of all Duracon® components falls into the zone where stress is virtually unaffected by changes in polyethylene thickness.

**Figure 6a**
Bartel’s data indicates that polyethylene thickness of greater than 6mm shows little increase in contact stress. All Duracon® Knee inserts have a minimum polyethylene thickness of 6.2mm.
A more recent paper by Bartel et al. examined several commercially available knees, rather than a single design as in the earlier paper. This work has shown that the effects of thickness are substantially influenced by optimizing articular design. In this study, the finite element method was used to calculate contact stress, maximum principal stress, and von Mises stresses throughout various implants. The occurrences of surface damage, such as pitting and cracking, have been associated with the maximum principal stress. The propagation of subsurface cracks is associated with the maximum shear or von Mises stresses. The methods used incorporated large-strain theory and a nonlinear material model for UHMWPE, which allowed investigators to more accurately estimate the stress state in the components.

Results of the nonlinear finite element analysis indicated that component thickness and conformity of the articulation surface play a significant role in the stresses developed in the components. The Duracon® Knee articular conformity throughout the range of motion demonstrated in the previous sections produced outstanding results in Bartel’s comparison of several total knee designs. The Duracon® design demonstrated very low stress (Figure 6b).

The results of Bartel’s work indicate that the Duracon® design, with its high level of conformity and minimum 6.2mm UHMWPE thickness, has a low contact stress, low maximum von Mises stress, and a low range of maximum principal stress. This independent study demonstrates that the design of the Duracon® Knee tibiofemoral articulation has achieved the extremely important goal of limiting polyethylene stress, and, thereby, improving TKA wear properties.
The intricate articular surface of the Duracon® Knee allows natural internal/external rotation, thereby reducing interface stresses.

In addition to assuring good tibiofemoral contact throughout the range of motion, the Duracon® Knee provides articular surfaces that consider two key factors in natural knee motion: internal/external rotation and anterior/posterior stability.

Internal/External Rotation
While addressing issues of conformity and contact, the tibiofemoral articulation of the Duracon® Knee does not lose sight of appropriate knee kinematics. Internal/external rotation is a key aspect of anatomic motion in the knee. The Duracon® Total Knee System components' range of motion was evaluated in the knee simulator (Figure 7) in the Biomechanics Laboratory at the Good Samaritan Hospital in Baltimore, MD. This device holds an intact cadaveric human knee, with the tibia totally unconstrained (except for its intrinsic anatomical soft tissue constraints). This knee simulator has been used previously to characterize various aspects of the biomechanics of the knee.13-15

The Duracon® tibial, femoral, and patellar components were implanted into a cadaveric human knee and mounted in the simulator. A constant physiological 150N axial load was applied across the knee. Flexion, internal/external rotation, and anteroposterior displacement were applied to the knee joint independently.

Figure 7
The Baltimore Knee Simulator used to evaluate knee biomechanics.
The curves of internal/external torque versus rotation angle at each position of knee flexion were converted to key data points. Results are graphically illustrated in Figure 8. The graph clearly demonstrates that the Duracon® Condylar and Duracon® A/P Lipped Inserts allow "virtually" normal knee rotation at all degrees of flexion tested. In fact, the rotational movement achieved in this study is well beyond the 17° seen in the normal knee. This occurs because the testing apparatus allows the cadaveric knee to reach the absolute, extreme limits of the joint motion. This test shows that it is only the soft tissue and kinematics of a given patient's knee that will limit the rotational motion of the Duracon® Knee. The natural, anatomic motion of the knee is attained with the Duracon® Knee prosthesis through the use of an advanced, 4-axis machining technology. This technology produces a tibial articulation surface with a unique rotary arc, which accommodates the screw-home mechanism of the natural knee and allows rotation of the femoral component. While allowing for physiological motion, the insert surface also has A/P and M/L contours that conform precisely to the radiused distal femoral condyles.

The ability of the Duracon® femoral component to internally/externally rotate within the range of a normal knee ensures that acceptable kinematics are achieved. This leads to reduced interface stresses; such reductions have been attributed to better wear properties and fewer component failures.

Internal/External Rotation Study

Figure 8
Internal/external rotation of the Duracon® Total Knee System Condylar and A/P Lipped components compared to the normal knee. As the results show, the Duracon® Knee allows motion that is very similar to the motion of the natural joint.
Resistance to Anterior Subluxation

The contribution which the posterior cruciate ligament makes to successful total knee arthroplasty has been debated for some time. It is generally accepted that if the PCL is compromised or sacrificed, additional A/P support is desirable. The Duracon® System offers two styles of inserts without a stabilizer post, the Condylar Insert and the A/P Lipped Insert. There is also a Stabilizer Insert style with an intercondylar post and a Total Stabilizer Insert for revision cases.

Using the biomechanical knee simulator described earlier, the curves for the anteroposterior force versus displacement at each angle of knee flexion were converted to key data points. Results are graphically illustrated in Figure 9.

The Condylar and A/P Lipped Inserts offer a high degree of conformity. The Total Stabilizer offers the highest degree of constraint. The articular design of the A/P Lipped Insert adds anterior/posterior constraint. The A/P Lipped Insert offers the anterior/posterior stability generally associated with a PCL-sacrificing post design, without the need for an invasive femoral resection. There is, also, the Stabilizer Insert with an intercondylar post for surgeons who prefer the use of stabilizer implants and for cases requiring the added assurance of the post. The Duracon® Total Stabilizer allows for proper constraint in difficult revision cases. The Duracon® A/P Lipped and Stabilizer Inserts offer important resistance to anterior subluxation, which can be vital when the PCL is compromised or sacrificed.

The physiological realities of total knee arthroplasty must be examined when designing a total knee. The tibiofemoral articulation of the Duracon® Knee has balanced the goals of conformity and contact with the need for maintaining good knee kinematics. To that end, rotational freedom and anterior/posterior stability have been addressed in the Duracon® Knee insert design. By considering the issues surrounding tibiofemoral articulation, the design of the Duracon® Knee allows physiological motion while maintaining good polyethylene wear properties.
ADDRESSING THE ANATOMIC REALITIES OF TOTAL KNEE ARTHROPLASTY

The articular design of a total knee system must address all of the complex issues of knee kinematics. The design must allow for physiological motion. To ultimately be effective, it must also consider the anatomic realities of the TKA patient. An initial development goal of the Duracon® Knee articular surfaces was to maximize the femoral-tibial size interchangeability. In this way, the patient’s anatomy would dictate the femoral and tibial sizes used, rather than the design limitations of the tibiofemoral articulation.

When introduced, the Duracon® Knee offered the greatest amount of femoral-tibial size interchangeability. As Figures 10a and 10b illustrate, the Condylar and A/P Lipped inserts can be matched with a femoral component that is two sizes larger or smaller than the inserts. The Stabilizer and Total Stabilizer inserts can be matched with a femoral implant that is one size larger or smaller than the insert. In some cases the Stabilizer can be used with a two-size mismatch.

All Duracon® Knee inserts have a common center. The articular surface radiuses out from the center. Thus, within the limits of the perimeter of the insert, substantial femoral-tibial size interchangeability can be obtained.

The tibiofemoral articulation of the Duracon® Knee offers substantial size interchangeability of the femoral and tibial components. In this way, the surgeon can choose the Duracon® Knee implant size based solely on the anatomy of the patient.

The Duracon® Knee allows for substantial size interchangeability of the femoral and tibial components.
The Duracon® Knee tibiofemoral articulation has achieved the ambitious goal: to provide excellent conformity throughout the range of motion while addressing physiological motion and patient anatomy. To obtain substantial conformity, while reducing contact stress, Duracon® Knee has:

- Large Contact Areas *Throughout the Range of Motion*
- Broadly Radiused Femoral Condyles – to reduce point contact even when malalignment occurs
- Generous Polyethylene Thickness

To address joint kinematics and knee physiology, the Duracon® Knee System offers:

- Internal/External Rotation equal to that of the normal knee
- Four Levels of Insert Constraint (Condylar, A/P Lipped, Posterior Stabilizer, and Total Stabilizer)
- Significant Femoral/Tibial Component Size Interchangeability

The Duracon® Knee tibiofemoral articulation has remained absolutely unchanged since its introduction. The design goals of this system have demonstrated their clinical importance beginning with the first implantation in 1991. The performance of the Duracon® Knee articulation surfaces in hundreds of thousands of cases worldwide has further strengthened the scientific merits of the design.
REFERENCES

5. Data on file at Howmedica Osteonics.
6. Fuji Photo Film Co., Ltd., Tokyo, Japan.
11. It should be noted that their analyses were all performed using linear elastic material properties for UHMWPE.
15. Hungerford DS, Kenna RV, and Haynes DW. Relevant Biomechanics of the Knee for Replacements. Total Knee Arthroplasty, Ch. 3, 210-234.