why iUni®?

CLINICAL RATIONALE FOR A PATIENT-SPECIFIC UNICOMPARTMENTAL KNEE REPLACEMENT SYSTEM
Key elements needed for a successful UKA:

The right patient, a highly reproducible procedure, and the right implant.

UKA can have favorable results vs. off-the-shelf TKA

Better function and ROM
UKA patients have better range of motion and function.\(^1\)
PKR tibial axial rotation is comparable to native knees, while TKR knees show a significant difference.\(^2\)
PKR patients have fewer problems bending their knee.\(^3\)

Patients prefer their PKR
In a study of 23 bilateral patients, >50% prefer their PKR implant to their TKR; none preferred their TKR.\(^4\)
In another study of 23 bilateral cases, patients reported PKR implants provide better early flexion, higher ROM and a more natural feel.\(^5\)

Survivorship can be comparable
PKR patients have better early function and maintain those advantages at 15 years vs. TKR, with no disadvantage on durability.\(^6\)
In a prospective study of 62 consecutive fixed bearing PKR procedures, survivorship was at 98% after 10 years.\(^7\)

UKA can require revision

Recent results from national registries and other multi-center studies reporting on causes of revision from over 6,500 primary fixed bearing UKA.

<table>
<thead>
<tr>
<th>Cause</th>
<th>ALS Registry(^7)</th>
<th>Norwegian Registry(^7)</th>
<th>Swedish Registry(^7)</th>
<th>Multi-Center Study(^7)</th>
<th>Single Center Study(^7)</th>
<th>Multi-Center Study(^7)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease Progression</td>
<td>14-50% (Range)</td>
<td>14-50%</td>
<td>14-50%</td>
<td>14-50%</td>
<td>14-50%</td>
<td>14-50%</td>
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<tr>
<td>Pain</td>
<td>NS-24%</td>
<td>NS-24%</td>
<td>NS-24%</td>
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<tr>
<td>Poly wear</td>
<td>2-21%</td>
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<td>2-21%</td>
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</tbody>
</table>

\(^1\) Other
\(^2\) Poly wear
\(^3\) Pain
\(^4\) Disease Progression
\(^5\) Loosening
The right UKA implant system must maximize the chance of procedural success and must minimize the chance of failure.

**Key drivers of a successful UKA procedure**

**Preventing failure from implant loosening and subsidence**
- Preventing malpositioned components and malaligned (varus/valgus) tibial resections
  - 24% of loosening is attributed to femoral and tibial component malposition or malaligned tibial resections.\(^1\)

**Maximizing tibial coverage**
- Poor tibial coverage, i.e. underhang, has been attributed to increased risk of tibial component loosening and subsidence.\(^2\)

**Preventing residual pain**
- Minimizing tibial overhang
  - ≥3mm of tibial overhang significantly increases risk for residual pain. In addition, overhang can result in putting increased stress on the MCL.\(^3\)

**Preventing patella track impingement**
- Studies have reported 28% of patients have patella impingement and increased pain while on stairs and rising from chairs.\(^4\)

**Minimizing disease progression and poly wear**

**Achieving proper mechanical axis alignment**
- Studies have reported that ‘slightly under-corrected’ UKAs result in less long-term progression of disease and poly wear.\(^5\)

**Achieving optimal function**

**Optimizing joint function and knee kinematics**
- It has been proposed that preservation of the joint line and the sagittal J-curve provide opportunity to preserve normal joint function, with potential to result in more normal knee kinematics.\(^6\)
Importance of tibial fit

Impact of Tibial Overhang

Overhang of \( \geq 3 \text{mm} \) has been shown to be clinically significant

- A study of 160 Oxford UKR patients demonstrated at 5 years post-surgery that 9% of patients have major overhang (\( \geq 3 \text{mm} \)) and significantly worse Oxford knee scores and pain scores.\(^{15}\)
- In a study with six cadavers, researchers identified that tibial trays with \( \geq 3 \text{mm} \) of anterior overhang result in significantly higher loads on the MCL.\(^{16}\)

iUni G2 solution: Unparalleled tibial fit

Key design features

- Implant profiles are patient-matched to provide >95% tibial coverage.\(^{20}\)
- Designed to sit within \( \approx 1 \text{mm} \) of cortical rim without overhang
- Tibial resection set at \( 90^\circ \) vs. mechanical axis
- Design set near tibial spine for large contact area

9% of patients have \( \geq 3 \text{mm} \) overhang with significantly worse knee and pain scores.\(^{15}\)
Impact of Tibial Underhang

Multiple publications have associated underhang with tibial loosening and subsidence

- Chau, et al., stated in UKA that “…concern with an under-hanging tray is that the load is transmitted primarily through the relatively weak cancellous rather than the stronger cortical bone. This may increase the risk of tibial component subsidence and loosening.”\textsuperscript{15}

- Swienckowski, et al., stated that in UKA “…cortical support is essential for the tibial components to avoid subsidence.”\textsuperscript{21}

- Fitzpatrick, et al., in a comparison of UKA designs, stated that “Unicompartmental components [have] less cortical bone available to the implant, increasing the risk of subsidence and overhang.”\textsuperscript{22}

iUni G2 solution: Optimal coverage

Key design features

- Each tibial tray and poly is created specifically for each patient
- Designed for optimal fit

Off-the-shelf UKA offers limited options

Typical configurations

- Offered in a single shape
- Come in a set range of sizes
- Surgeon may need to prioritize either A/P or M/L fit

Highlighted area in pink represents 1.5mm cortical rim thickness\textsuperscript{22}
Importance of femoral fit

Impact of Femoral Fit on Patient Pain

Malaligned femoral components can cause loosening
A study of 47 UKA failures during the period of 2000-2008, identified that 16% were attributed to femoral malposition or sizing issues.14

Patella impingement can cause increased pain
A study of 99 UKA knees at mean 14 year follow-up identified that 28% had patella impingement and increased pain, typically when on stairs and rising from chairs.17

iUni G2 solution: Unparalleled femoral fit

Key design features

- Implant set at ~1mm inferior to sulcus terminalis for optimal coverage while staying outside patella track
- Tapered anterior edge set into subchondral bone
- Component set ~1mm from edge for optimal fit without overhang
- Femoral pegs centered on condyle
- Femoral pegs are 22° vs. mechanical axis to prevent "pistoning effect"
Impact of Femoral Fit on Function

Anatomy of the femur varies
Femoral condyles have an asymmetrical shape and vary from patient to patient.\textsuperscript{24}

Off-the-shelf systems offer limited options
A typical UKA system has the following femoral component configuration.
• A single shape
• A set range of sizes

iUni G2—an opportunity to maintain patients’ anatomy

Key design features

Green line represents patient’s sagittal J-curve at articulating surface level

Femoral component thickness approximates average cartilage thickness on the femur

Femoral component follows bone topography of the medial or lateral condyle, preserving the patient’s natural sagittal curve
Impact of implant design on long-term outcomes

Mechanical Axis Alignment Can Impact Disease Progression and Polyethylene Wear

Slight ‘undercorrection’ can provide optimal results

• Studies have shown ‘slight undercorrection’ (e.g. between 171° to 179° post-operative varus angle in a medial UKA) can provide optimal results.25

• A follow-up study of 58 medial uni knees with mean 15 year follow-up, reported that ‘overcorrected’ knees (e.g. post-operative valgus angle in a medial UKA) had 92% more cartilage loss in the opposite condyle.25

• In the same study, ‘significantly undercorrected’ knees (e.g. ≤170° post-operative varus angle in a medial UKA) had 50% more poly wear vs. ‘slight undercorrection’.25

iUni G2 solution: Intra-operative soft-tissue balancing

Key design features

Balancer chips, based on pre-op CT, set ligament tensioning and establish tibial resection depth prior to performing resections

Vertical resection is set parallel to tibial spine and designed to be near the ACL

Horizontal resection is set at 90° vs. tibial mechanical axis

Posterior slope is patient-matched and pre-navigated

Slight under-correction provides optimal axis alignment
Other Factors Impacting Polyethylene Wear

Contact stress can impact topside wear
Reducing contact stress has been shown to reduce wear on the articulating surface of the poly insert.\textsuperscript{26}

Poly/tray micro-motion and undersurface can impact backside wear
Studies have shown micro-motion can cause wear. In addition, examinations of explanted inserts have identified the poly undersurface as a second source of wear.\textsuperscript{27, 28}

Micro-motion Index Comparison

<table>
<thead>
<tr>
<th></th>
<th>Standard\textsuperscript{29,30} vs. ConforMIS G2 implants\textsuperscript{31}</th>
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<tr>
<td>Femoral component and poly surface</td>
<td>has a matched 1-to-5 ratio of increased contact area and less contact stress\textsuperscript{26}</td>
</tr>
<tr>
<td>Interference fit of tibial insert</td>
<td>minimizes micro-motion and, combined with the highly finished inside pocket, potential for backside wear\textsuperscript{31}</td>
</tr>
</tbody>
</table>

iUni G2 solution: Engineered femoral and tibial components

Key design features
So, why iUni?

FIT
• Individualized fit that virtually eliminates overhang and sizing compromises
• Designed to follow the contour of each patient’s anatomy
• Tibial tray designed for maximized cortical rim coverage and proper rotational alignment

SHAPE
• Individualized medial or lateral femoral J-curves
• Wear optimized by matching femur and tibial inserts for maximized surface contact area

SIMPLE SURGICAL TECHNIQUE
• Reduced number of intra-operative decisions such as implant sizing and rotation
• Mechanical and rotational alignment are pre-determined in the individualized iJig instrumentation
• iView surgical planning images for proper iJig placement and detailed resection values

OR EFFICIENCIES
• Simplified set-up and tear down
• Minimal instrumentation required
• Disposable system delivered in a single pre-sterilized box
• Reduced sterilization and inventory costs
20. ConforMIS data on file
21. Swiancikowski, J., et al.; “Unicompartmental Knee Arthroplasty in Patients Sixty Years of Age or Younger”; JBJS,2004
23. ConforMIS data on file
29. J. Slamin. A new cobalt chrome tibial tray and moderately cross-linked tibial insert is added to the PFC Sigma modular knee system, Slamin, DePuy Orthopaedics, Inc.; Technical Paper, 2005