Customized Patient Specific Implants and Instruments

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Disclosures

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Why Customize and Individualize?

*Primary Drivers of Patient Dissatisfaction*

- Functional limitations due to poor kinematics
- Residual pain resulting from imperfect fit
- Pain from component malrotation

Hypothesis - Restoration of Anatomy

kinematics-function-satisfaction
CT Image to Implant delivery model

Femoral components custom printed ‘wax-investment’ ceramic molding
Partial Knee Resurfacing

- iUni Unicompartmental
  - Medial, Lateral

- iDuo Bicompartmental
  - Medial PF, Lateral PF
Implant profiles are patient-matched to provide >95% tibial coverage.

Exact tibial fit
Patient-specific fit & positioning

Examples of tibial anatomical variability from consecutive cases

- Designed to sit within ≈1mm of cortical rim without
- Design set near tibial spine for large contact area
Patient Specific TKA
OR Experience-Precise printed individualized Nylon jigs

iUni

iDuo
OR Experience - Printed individualized Nylon Jigs

**Primary Benefits:**
- Reduced steps and trialing
- Reproducible technique via printed iJigs
- Simplified, integrated balancing
- Short learning curve
- Highly efficient OR management - no inventory
- Ideal for Outpatient Surgery Center

**Primary Drawbacks:**
- Cartilage removal
Patient-specific implants for lateral unicompartmental knee arthroplasty

Marco K. Demange · Arvind Von Keudell · Christian Probst · Hiroshi Yoshioka · Andreas H. Gomoll

Compared 33 lateral iUni to 20 ZUK for lateral OA

Tibial coverage mismatch 1.0mm CIM-3.3 mm OTS(p<0.01)

97% Survivorship 37mos versus 85% 32 mos CIM versus OTS

CIM better tibial coverage and excellent short term improvement
Impact of tibial fit on intra-operative compromise

Patient-specific fit & positioning

Off-the-shelf UKA system

ConforMIS iUni G2
45 YO Female disabling B Knee OA
Post op Medial iDuo G2
Bilateral Lateral + PF OA 58 YO female
Post op B Lateral iDuo
iDuo G2 Experience
9-2010 to 2-2016

- 55 patients with 59 knees
- Average F/U 45 MO, (12-72 MO)
- Average age 51 years old, (range 37-65)
- 41 multiply operated AV 3.2 surgeries
- 35 females, 24 males
- 41 medial, 18 lateral iDuo’s
## Clinical Outcomes, n=56

<table>
<thead>
<tr>
<th>Rating system</th>
<th>Preoperative</th>
<th>Final follow-up</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modified Cincinnati</td>
<td>1.9 ± 0.9</td>
<td>6.2 ± 1.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>VAS</td>
<td>6.1 ± 2.1</td>
<td>1.9 ± 1.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>WOMAC total</td>
<td>36.4 ± 16.6</td>
<td>25.4 ± 15.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>WOMAC – pain</td>
<td>8.3 ± 3.7</td>
<td>4.9 ± 3.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>WOMAC – stiffness</td>
<td>3.6 ± 1.8</td>
<td>2.8 ± 1.5</td>
<td>0.0022</td>
</tr>
<tr>
<td>WOMAC – function</td>
<td>24.5 ± 12.1</td>
<td>18.1 ± 11.3</td>
<td>0.0015</td>
</tr>
<tr>
<td>SF-36 – PCS</td>
<td>38.6 ± 7.2</td>
<td>47.6 ± 8.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>SF-36 – MCS</td>
<td>40.5 ± 6.7</td>
<td>52.3 ± 10.0</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Summary Custom Individualized Bicompartmental Arthroplasty

• In a young population, 50.7 yrs. average, good bone and ligament preservation
• Acceptable survivorship 96% at 2 years and 94% at 5 yrs
• 91% patient satisfaction, G/E results
• Excellent pain relief VAS 6.1 to 1.8
• Excellent function Mod Cinc 1.9-6.2
• Despite 18 patients (22%) — arthroscopic lysis of adhesions for stiffness or mechanical symptoms, these were multiply operated knees
What has really changed in TKR since the 1980’s?
Symmetric CR “Off the Shelf” Implant

18 mm IC distance for Patella tracking in deep flexion
• Overhang on PCL
• Uncovered MFC
Anatomical Joint line restoration - medial and lateral
distal and posterior
Customized Individual TKA System

Will anatomical restoration “Form = Function”  
Kinematics = Satisfaction?

- Patient-Specific Fit
- Restoration of Articulating Geometry – J Curves, medial and lateral joint lines and offsets
- Dual Tibial inserts
- Restore ligaments to original state
- Mechanical Axis Alignment
- Bone Preservation – 30-40%
- Complete bone coverage-minimal blood loss
Virtual Alignment_CT Guided Pre-operative

**BEFORE**

![Before Image]

**AFTER**

![After Image]

The patient’s deformity is ‘Virtually Realigned’ prior to the design process starting. Correction is to mechanical alignment.
• CT Based Jigs

• 13 Cadaver legs

• Postop axial alignment within 1.2 degrees of neutral
Pre-navigated individualized Jigs

Efficient, Pre-Sterilized, Disposable

Single use kit delivered a few days before surgery
iTotal Patient Specific Surgical Plan  

Femur

Serial Number: 0011044  Knee: Right

Femoral Images

Femoral Position:
Properly positioning F3 will result in a pair of distal femoral cuts that are perpendicular to the mechanical axis in the coronal plane.

Proposed Distal Femoral Cuts

Proposed Femoral AP Cuts
Image has femoral osteophytes removed. Resection values reflect placement of the AP cut guide such that the anterior and posterior resection planes are parallel to the transseamondylar axis.

Proposed Implant Placement (Images do not include osteophyte information):

Notes: Bone resection values do not include cartilage thickness or account for bone lost to ixyx blade cut.
iTTotal Patient Specific Surgical Plan  iView 2.0  Tibia
51 YO male 3 mos post op
4 mos post op - 59 year old Male
54 YO Female 1 yr post op
48 YO Male  1yr post op
Advanced 21 degree Varus
21 Degree Varus post op
Axial Alignment after 21 degree correction
20 degrees Valgus
Postop Valgus Knee
Series CIM TKA
5-2011 and 4-2016

- 201 patients, 232 knees
- Average age 56.9 (range 30-76 years old)
- BMI= 31.1 (range 18.7-59)
- Average follow up 34.9 months (12-72)
- 100% F/U
## Outcomes Stratified by Age

<table>
<thead>
<tr>
<th></th>
<th>Overall (n = 232 knees)</th>
<th>&lt;40 (n = 11 knees)</th>
<th>41-50 (n = 52 knees)</th>
<th>51-60 (n = 89 knees)</th>
<th>&gt;61 (n = 80 knees)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Average age</strong></td>
<td>56.9</td>
<td>36</td>
<td>47</td>
<td>56</td>
<td>67</td>
</tr>
<tr>
<td><strong>Female/male</strong></td>
<td>134/98</td>
<td>4/7</td>
<td>33/19</td>
<td>59/30</td>
<td>38/42</td>
</tr>
<tr>
<td><strong>Average BMI</strong></td>
<td>31.1</td>
<td>30.9</td>
<td>33</td>
<td>31.1</td>
<td>29.9</td>
</tr>
<tr>
<td><strong>Failed knees</strong></td>
<td>10</td>
<td>1</td>
<td>0</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td><strong>Failure rate</strong></td>
<td>4.3%</td>
<td>9%</td>
<td>0%</td>
<td>6.7%</td>
<td>3.8%</td>
</tr>
</tbody>
</table>
Outcomes CIM TKA

- Survival rates were 98% and 92% at 2 and 5 years.
- 10 knees (4.3%) required revision TKA at 35 mos range 18-61.
- All functional outcome scores significantly improved postoperatively (p < .05).
- 87% rated their knees as good or excellent.
- 90% patient satisfaction.
**iTotal CR in the UK National Joint Registry: Beyond Compliance**

- Mean Follow-up: 1.9 years (max: 5.6 years)
- 576 procedures at 46 centers
- 3 revisions reported to date
- 0.5% revision rate @4 years compared to 1.9% revision rate for all TKRs in the NJR.

![Graph showing revision rates](image-url)
Experience to date 2011-2018

EXCELLENT FIT AND COVERAGE FOR VERY SMALL OR LARGE PATIENTS
MINIMAL BLOOD LOSS
JIGS ACCURATE
TRUST TRIALS AND REMOVE ALL OVERHANGING OSTEOPHYTES
MINIMAL SOFT TISSUE BALANCING
EXCELLENT INTRAOP STABILITY WITH NO MIDFLEXION LAXITY
EASE FOR OR STAFF
DISCHARGE HOME DAY 1-2 POST OP
EXCELLENT EARLY PATIENT SATISFACTION