

why iTotal®?

CLINICAL RATIONALE FOR A PATIENT-SPECIFIC
CRUCIATE-RETAINING KNEE REPLACEMENT SYSTEM



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CAUTION: USA federal law restricts this device to sale by or on the order of a physician. The Conformis Cruciate Retaining Total Knee Replacement System (iTotal CR) is intended for use only by fully trained physicians. Prior to use of a Conformis device, please review the instructions for use and surgical technique for a complete listing of indications, contraindications, warnings, precautions, and directions for use.



1 in 5 patients are not satisfied

with the results of their total knee replacement.¹



Over 5 million people are living with total knee replacements.⁹ Therefore, millions are likely dissatisfied with their knee replacement. This number continues to grow as over 1.2 million knee replacement procedures are done every year worldwide.¹⁰

Leading Causes of Patient Dissatisfaction

Residual Pain

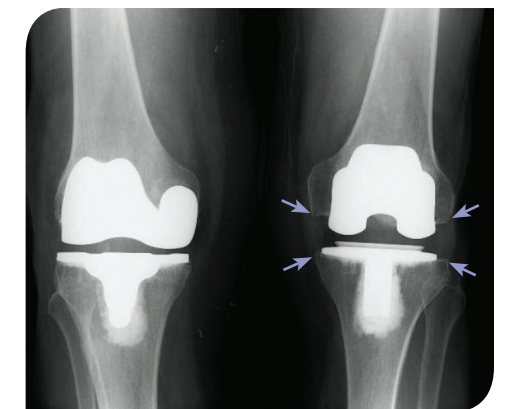
- **Fit:** Data suggests that 27% of clinically significant knee pain is attributable to femoral implant overhang.¹¹
- **Rotation:** Internal rotational errors, particularly of the tibial component, are a major cause of pain and functional deficit after TKA.¹²

Functional Limitations

- **Poor Function:** Patients who have a TKR experience substantial functional impairment compared to their peers without a TKR.¹³
- **Unnatural Feel:** 46% of dissatisfied patients state their knee does not feel normal. Even amongst satisfied TKR patients, 20% state their knee does not feel normal.⁶

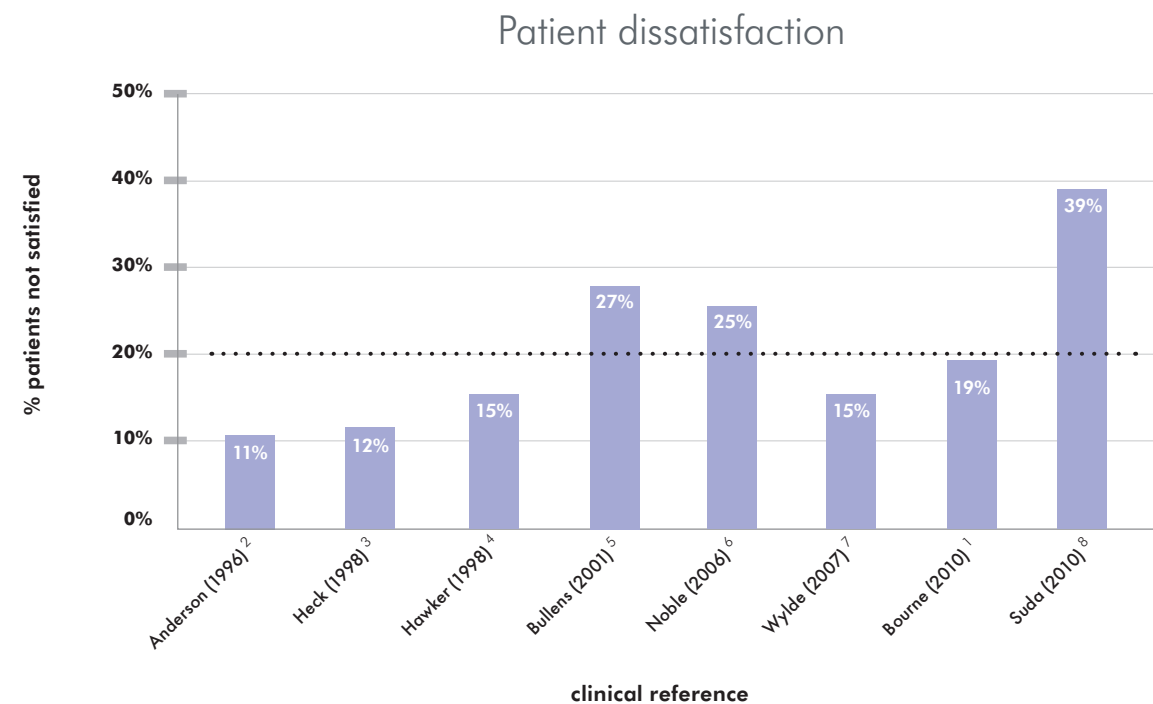
Early Implant Failure

- 50% of early revision TKA are related to instability, malalignment and failure of fixation.¹⁴



iTotal CR

Off-the-shelf



Residual pain: Improper fit

Implant overhang causes residual pain and dissatisfaction

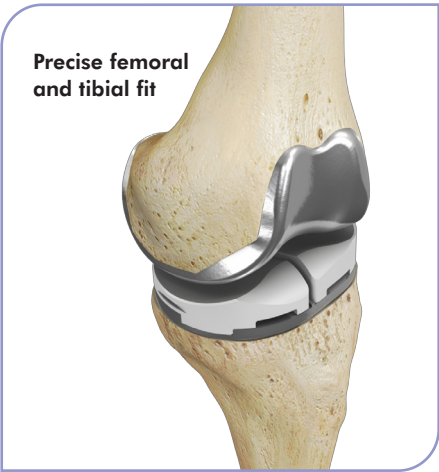
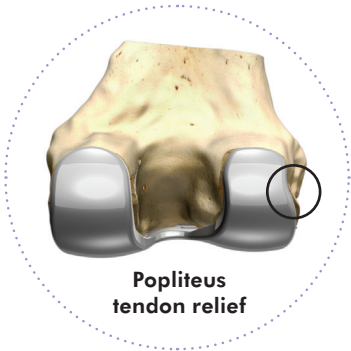
Off-the-shelf total knees force compromises between sizing and coverage. Variations in anatomy make it virtually impossible for off-the-shelf designs to fit the femur.

- In a series of 437 TKR femoral components, 68% of women and 40% of men had overhang of $\geq 3\text{mm}$. Overhang was correlated with a 1.9x increase in the risk of pain.¹¹
- Impingement of the femoral component can cause a snapping of the popliteus tendon which may be painful or disconcerting to the patient.¹⁵

The iTotal CR Solution: Individualized Fit

iTotal CR is uniquely qualified to address the wide variation in patient anatomy that lead to overhang and undercoverage. The individualized design is so precise that it virtually eliminates sizing compromises common with off-the-shelf knee replacements.

1.9x
increase in the risk of
pain with overhang¹²

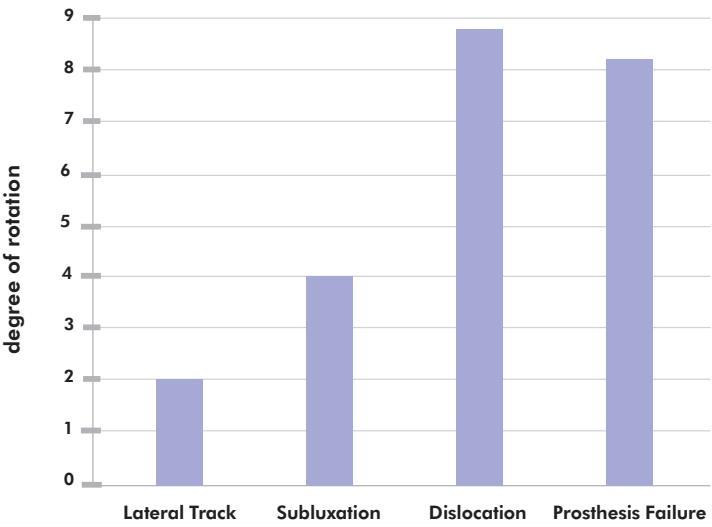


Rotational errors

Component malrotation is a leading cause of residual pain

- Among painful knees, 44% were found to have significant rotational errors of the tibial tray.¹⁶
- Off-the-shelf tibial component designs maximize coverage at the expense of proper rotational alignment. One study of 120 tibial components found that only 30% were aligned within $\pm 5^\circ$ of proper rotation.¹⁷
- In a study of anterior knee pain, patients with excess internal component rotation were more than 5x as likely to experience knee pain versus a control group.¹⁸

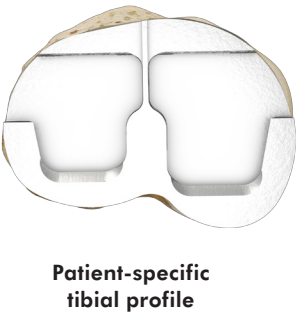
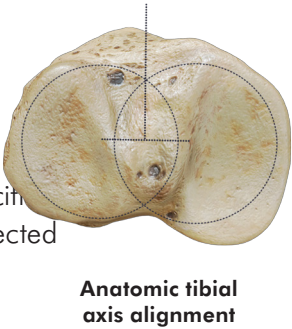
5x
as likely
to experience
knee pain if excess
internal component
rotation
is present¹⁸



There is a direct correlation between combined internal component rotation with the severity of patellofemoral complications.¹²

The iTotal CR Solution: Pre-navigated tibial rotation

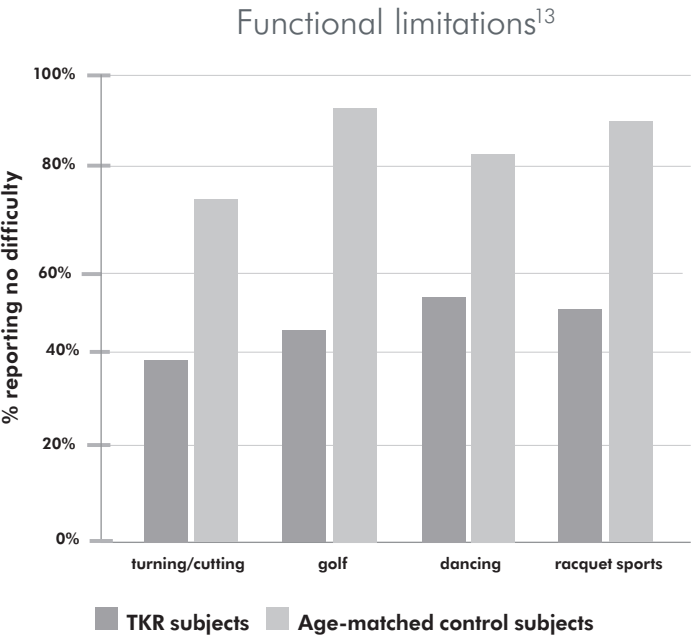
- Proper tibial rotation based on pre-operative CT scan and patient-specific shape matched to the profile of the resected tibia.
- In a study of 44 patients



Functional limitations: Poor kinematics and mid-flexion instability

Unnatural feel and poor kinematics lead to patient dissatisfaction

- According to published data, 2 to 3 times as many patients with TKA report some degree of difficulty with activities relative to a similar control group.¹³
- Off-the-shelf total knee implants, including single radius designs, have been shown to alter kinematics.¹⁹



Instability leads to patient dissatisfaction

- Studies of early implant failures have shown that instability accounts for as much as 27% of revision surgeries.²⁰
- Joint line movement of over 5mm has been shown to result in mid-flexion instability.²¹

In one study, dissatisfied patients reported that their knee did not feel normal at **more than twice** the rate of satisfied patients.⁶

3.7x increase in the risk of implant failure with ligament instability²²

The iTotal CR Solution: Patient-specific J-curves

iTotal CR is intended to restore each patient's natural articulating geometry by:

- Using the patient's natural medial, lateral and patellofemoral J-curves, corrected for deformity, as the basis for femoral implant design.
- Facilitating proper balancing of offset femur and joint line with femur-matched offset polys.
- Reducing lateral constraint to facilitate rollback.



Patient's natural J-curves

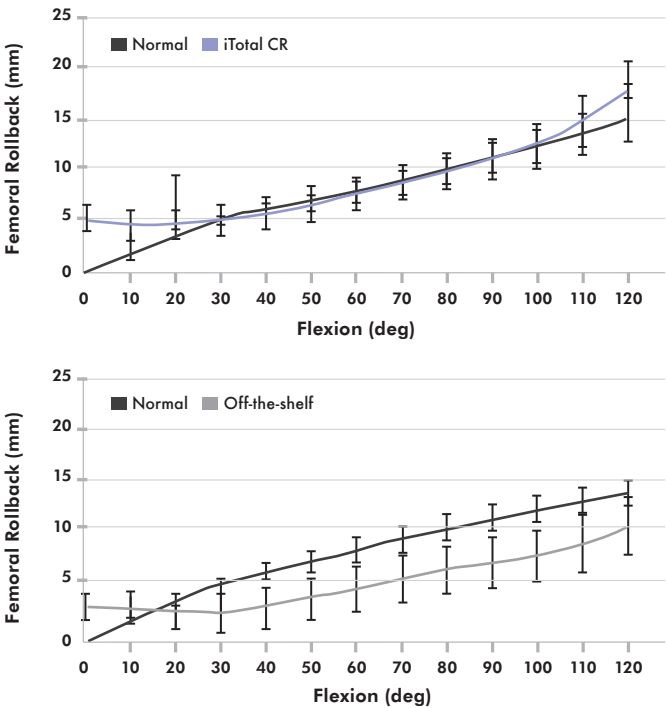
In a study comparing iTotal CR to an off-the-shelf TKR, iTotal restored natural kinematics:

- iTotal more closely approximated each patient's normal femoral rollback throughout ROM, an important feature of healthy kinematics.
- iTotal resulted in varus-valgus laxity, as measured by adduction/abduction, that was significantly closer to the normal knee.²³

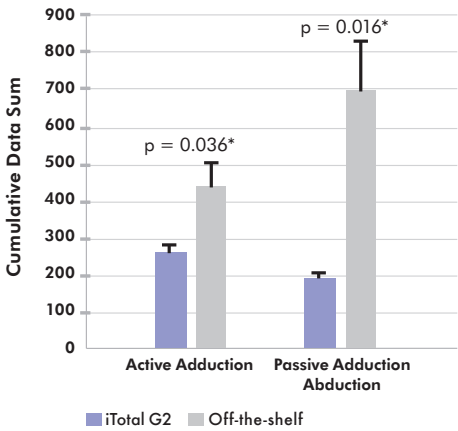


Dual inserts respect each patient's joint line

Average femoral rollback for iTotal CR and off-the-shelf TKR



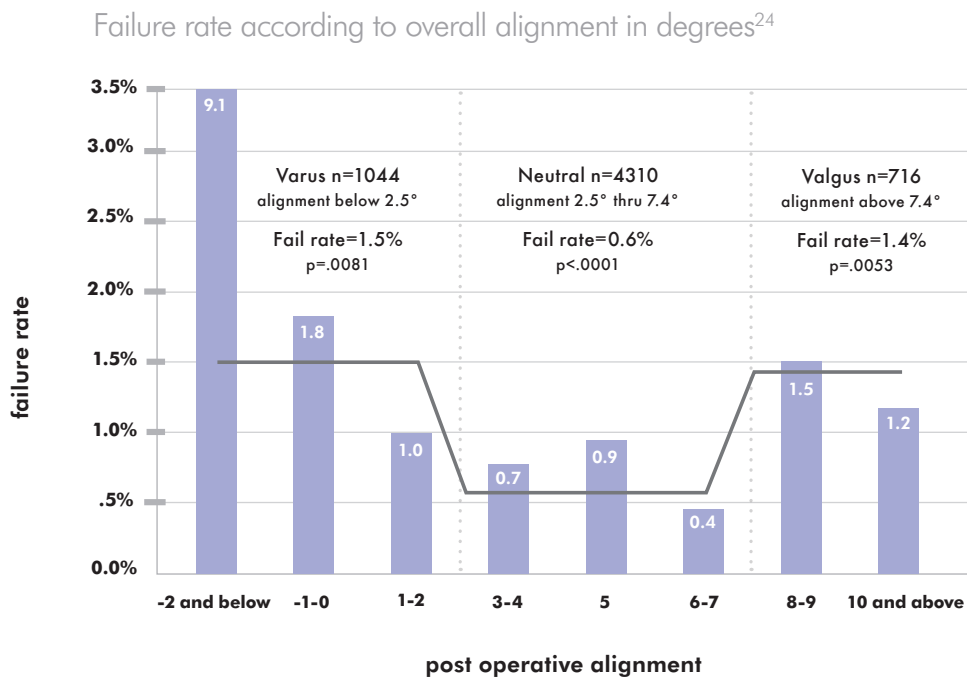
Varus/valgus laxity, post implantation



Early implant failure: Poor alignment

Cause of early implant failure: Poor overall alignment

- Studies have shown that varus tibial malalignment (<90°) was associated with a 10.6x greater risk of failure, while >8° valgus femoral malalignment was associated with a 5.1x greater risk of failure.²⁴



The iTotal CR Solution: Mechanical axis alignment

iTotal CR is intended to achieve neutral mechanical alignment:

- iFit® image-to-implant™ technology virtually aligns to mechanical axis using anatomic landmarks (center of hip, femur, tibia and ankle).
- Patient imaging data is used to create a 3D representation of the patient's anatomy to design accurate patient-specific implants and iJig® instrumentation with built-in neutral mechanical alignment.

Polyethylene wear

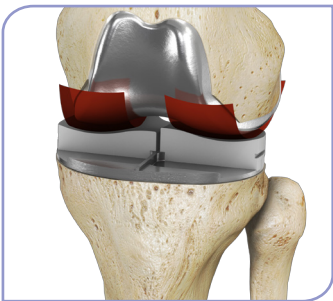
Cause of implant failure: Polyethylene wear

- Significant polyethylene wear was observed in 25% of revision surgeries, making it the most prevalent mechanism of implant failure.¹⁴

Overall causes of revision surgery ¹⁴	Percentage
Polyethylene wear	25.0
Loosening	24.1
Instability	21.2
Infection	17.5
Arthrofibrosis	14.6
Malalignment or malpositioned	11.8

The iTotal CR Solution: Engineered for low contact stress

- Due to its broad coronal radius, iTotal CR allows for high contact area with low constraint.
- The coronal radius on the femur interfaces with the poly throughout the range of motion.



Contact area (mm²) at 0°, 60° and 90° of flexion



So, why iTotal?

Designed with features to address the leading causes of patient dissatisfaction, iTotal CR is the only individualized total knee system on the market today.

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 coverage and proper rotational alignment

SHAPE

- Individualized medial, lateral and patellofemoral J-curves with matching offset poly inserts
- Designed for optimal bone preservation
- 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

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