



# Why Are So Many People Unhappy With Their Knee Replacement?

*...And what is ConforMIS doing to fix it?*

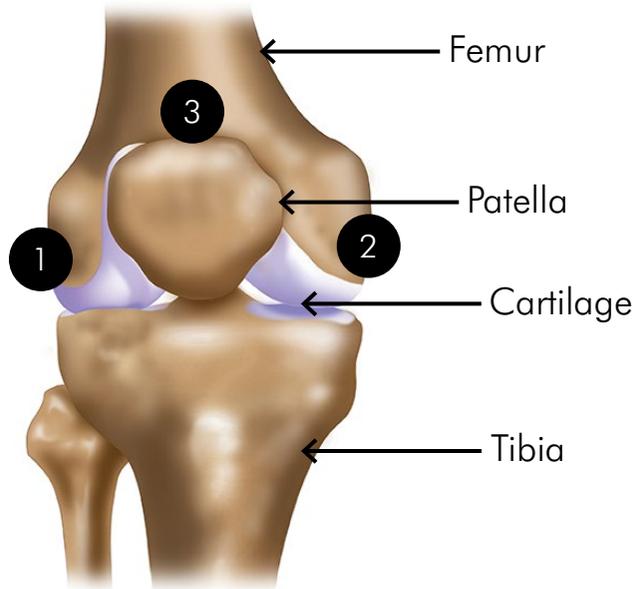
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# Anatomy

## Anatomy of the Knee



Your knee also has three compartments:

- 1 **Lateral** compartment (outer half of your knee)
- 2 **Medial** compartment (inner half of your knee)
- 3 **Patellofemoral** compartment (behind the knee cap)



Osteoarthritis in the medial or lateral compartment  
**(Unicompartmental)**



Osteoarthritis in the medial or lateral, plus patellofemoral, compartments  
**(Bicompartmental)**



Osteoarthritis in all three compartments  
**(Tricompartmental)**

## GLOSSARY

**Osteoarthritis:** a form of arthritis caused by chronic degeneration of the cartilage in the knee joint

**Cartilage:** a tough, rubbery supportive tissue on the ends of bones that reduces friction during movement

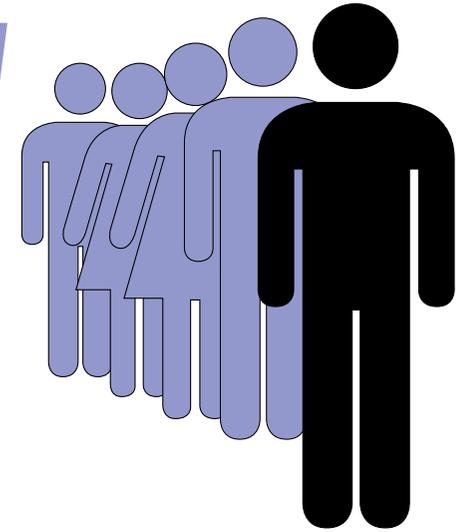
**Femur:** the largest and strongest bone in the body; the thigh bone

**Tibia:** the larger, heavier bone of the lower leg; the shin bone

Listen to Dr. Gregory Martin, Medical Director at the Orthopedic Institute of JFK Medical Center, overview the anatomy of the knee

Over 5 million people are living with total knee replacements.<sup>1</sup>

**1 in 5** of those patients are *not satisfied* with their results



What are the leading causes of dissatisfaction?

Pain After Surgery

Functional Limitations

Early Implant Failure

# Pain After Surgery

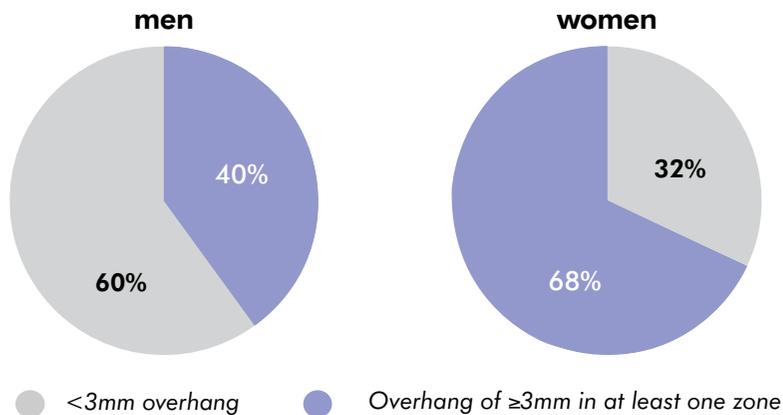
## Poor Implant Fit

Poor implant fit can result in **overhang**, which causes pain and dissatisfaction after surgery.

Every knee has a unique shape and size and its virtually impossible for off-the-shelf designs to fit each one. The result is oftentimes implant overhang, which can be painful because the metal rubs against the surrounding soft tissues.

### Overhang Is Common

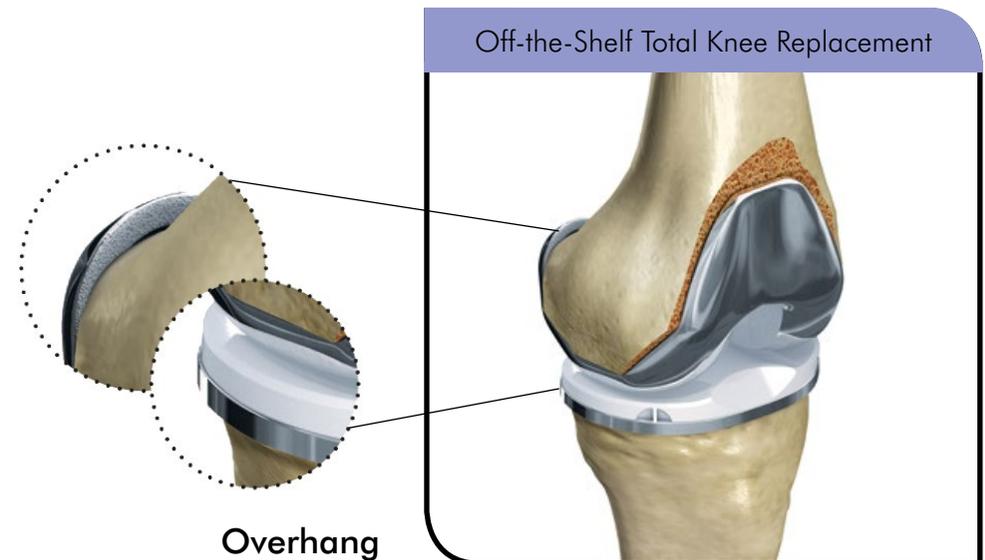
- In a study of 437 knee replacements, **57% of patients had overhang  $\geq 3\text{mm}$  on the femoral component.**<sup>2</sup>



### Overhang Is Painful

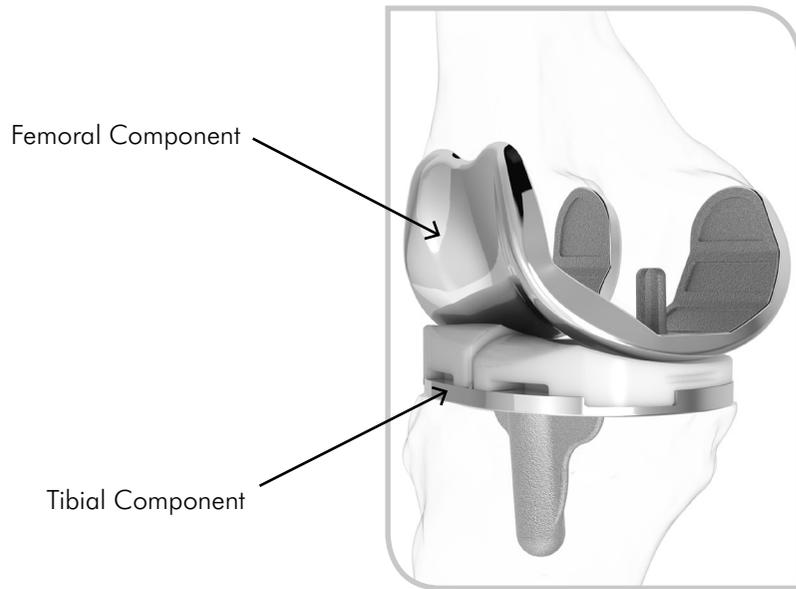
- 27% of clinically significant knee pain is caused by femoral implant overhang.<sup>2</sup>

Overhang was correlated with a **90% increase in the risk of pain.**<sup>2</sup>



# Pain After Surgery

## Rotational Errors

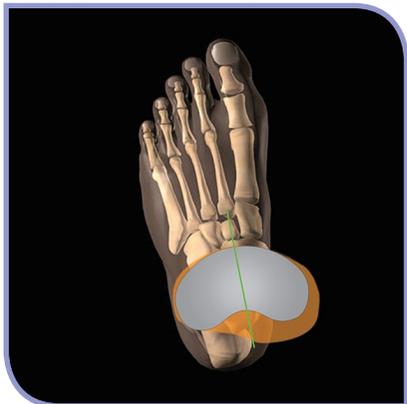


**Component malrotation is a leading cause of pain after surgery.**

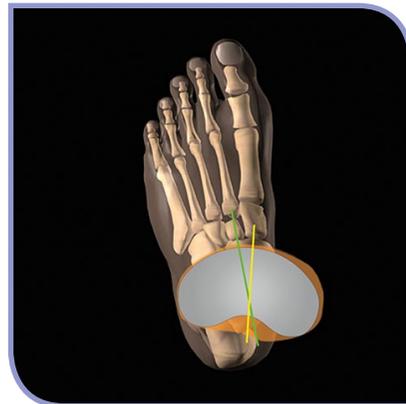
Because off-the-shelf implants don't always fit correctly, surgeons often have to compromise on the rotational alignment of the implant in order to achieve the best possible fit.

- In one study, 56% of knees with pain after surgery were found to have rotational errors of either the femoral or tibial component.<sup>3</sup>

Off-the-shelf implants force compromises on tibial component rotation



This implant is properly rotated; however, it leaves a lot of bone uncovered.



This implant covers the bone well, but it is not rotated properly.

- Bone
- Implant
- Correct rotation
- Actual rotation

You are **5x as likely** to experience knee pain if excess internal component rotation is present.<sup>4</sup>

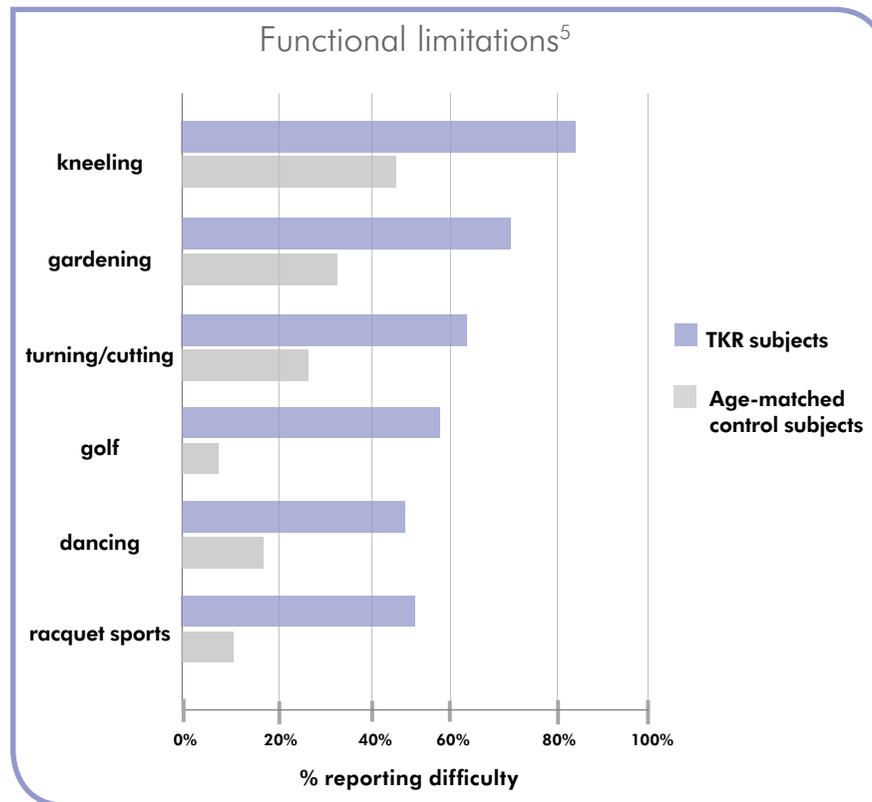
# Functional Limitations

Poor Function

*Unnatural feel* and *poor function* lead to patient dissatisfaction.

Off-the-shelf total knee implants are shaped differently than your actual knee, which can limit movement or make your knee feel unnatural.

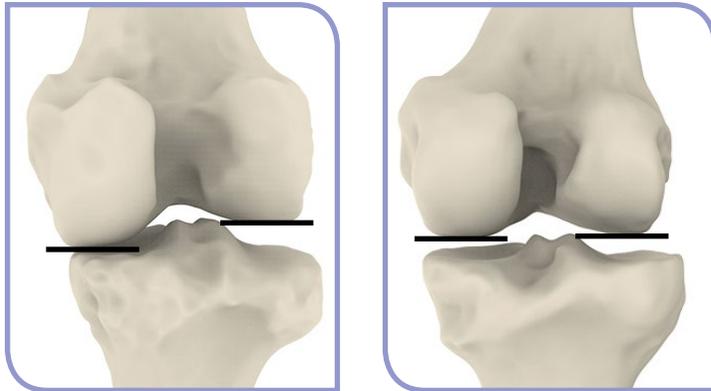
- 2 to 3 times as many patients with a total knee replacement report some degree of difficulty with activities relative to a similar control group.<sup>5</sup>



**DID YOU KNOW?**  
Dissatisfied patients reported that their knee did not feel normal at **more than twice** the rate of satisfied patients.<sup>6</sup>



A lesson in knee anatomy...



Patient A

Patient B

The knee has a naturally occurring offset. This offset creates what is called the **joint line**. Some people have a large offset, which means that the medial condyle, or the inside of the knee, is lower than the lateral condyle, or the outside of the knee (Patient A). Other people have a fairly flat joint line (Patient B). Maintaining the patient's natural joint line is very important in knee replacement surgery. If this isn't done correctly, the patient may experience **mid-flexion instability**. This means that at the point between complete flexion and extension, or when your knee is slightly bent, you may feel instability in your knee.

**Instability** leads to patient dissatisfaction.

Joint line movement has been shown to change how the knee moves and lead to mid-flexion instability. Off-the-shelf knee implants aren't designed to match the normal offset joint line that most patients have. Instead, they flatten the offset to the same height.

- Studies of early implant failures have shown that instability accounts for as much as **27%** of revision surgeries.<sup>7</sup>

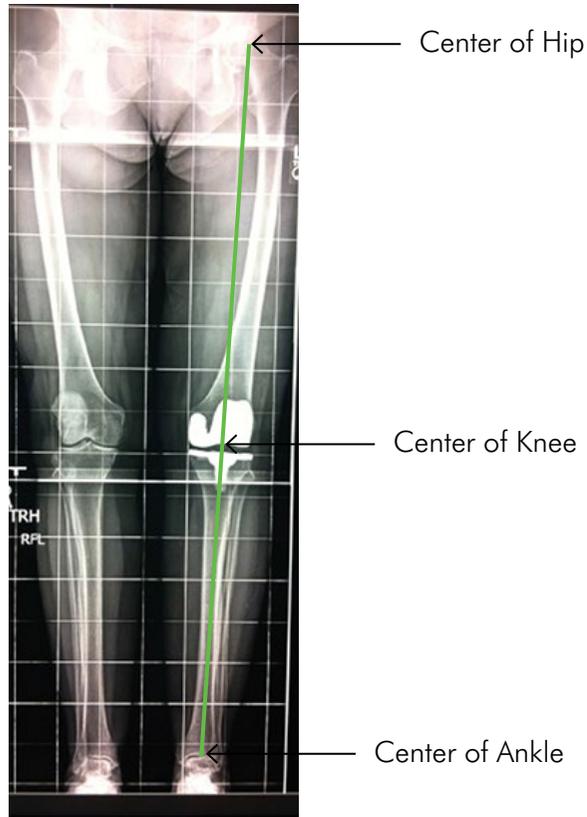
**DID YOU KNOW?**

You have a **3.7x** increase in the risk of implant failure with instability.<sup>6</sup>

# Early Implant Failure

## Poor Alignment

A lesson in knee anatomy...



An important step in knee replacement surgery is to align the knee along the **neutral mechanical axis**, which is shown in green in the diagram above. This axis is a straight line drawn through the center of the hip, knee, and ankle.

**Poor overall alignment is a cause of early implant failure.**

Proper alignment to neutral mechanical axis is associated with increased stability and a lower rate of implant component loosening.<sup>8</sup> However, proper alignment is often sacrificed to make off-the-shelf implants fit as best as possible.

**Poor alignment is associated with greater failure risk:**

- 10.6x greater risk of failure of the tibial component.<sup>8</sup>
- 5.1x greater risk of failure of the femoral component.<sup>8</sup>

### DID YOU KNOW?

Incorrect alignment is the cause for **11.8%** of revision surgeries.<sup>9</sup>

# The ConforMIS Approach

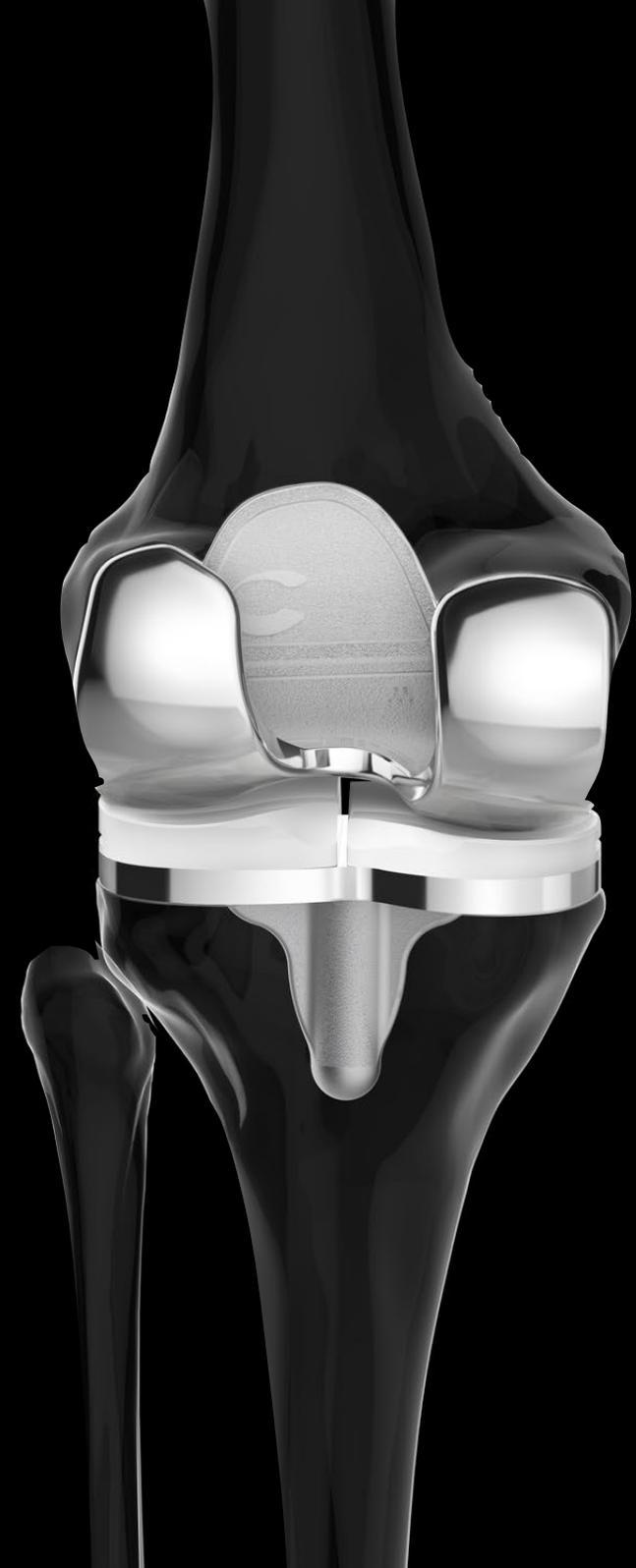


ConforMIS recognizes the limitations associated with off-the-shelf total knee replacement. This is why we design and manufacture **customized knee implants** and surgical instrumentation that are unique to your knee's natural shape and size. We believe that this customized approach could help reduce the 20% dissatisfaction rate with total knee replacement surgery.

CAUSES OF DISSATISFACTION	THE CONFORMIS APPROACH
<b>Poor Implant Fit</b>	ConforMIS implants are designed based off a CT scan to fit the unique size of each patient's femur and tibia. This virtually eliminates sizing compromises that could result in painful implant overhang.
<b>Rotational Errors</b>	Proper rotation of ConforMIS implants is determined prior to surgery based on a pre-operative CT scan. Implants are then designed with precise fit and with proper rotation built in. As a result, there is less risk of the surgeon having to compromise between fit and rotation.
<b>Poor Function and Mid-Flexion Instability</b>	ConforMIS implants restore each patient's natural shape by replicating the unique curves of their knee. By replicating these curves, we also maintain the patient's natural joint line, which can increase the potential for a more natural feeling knee and restore function.
<b>Poor Alignment</b>	iFit® Image-to-Implant® technology determines the mechanical axis of the knee using the center of the hip, femur, tibia, and ankle shown in the pre-operative CT scan. Patient-specific implants are designed with built-in alignment to this mechanical axis.

# References

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**CAUTION:** The iTotal CR Knee Replacement System (KRS) is intended for use as a total knee replacement in patients with knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only one or two of the three compartments. Only a licensed physician can help you determine the appropriate medical treatment. There are potential risks to knee replacement surgery, and individual results may vary. Before making any decisions concerning medical treatment, consult your physician regarding your options and the risks of those options. The longevity, performance and feel of any knee implant will depend on various factors, including your physical condition, your activity level, adherence to your physician's instructions, and other factors.

USA federal law restricts this device to sale by or on the order of a physician.

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