



CORI[®] Robotic-Assistance

Knee Arthritis and Treatment Options

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Today's Topic: CORI^o Robotics

A breakthrough technology that uses computer and robotic assistance to achieve accurate and individualized results^{1,2}



1. Lonner J., Smith J., et al., High Degree of Accuracy of a Novel Image-free Handheld Robot for Unicondylar Knee Arthroplasty in a Cadaveric Study. Clin Orthop Relat Res 2014 Jul 8. Epub 2014 Jul 8.
2. Data on file. Internal doc number TR0923

Slide 2

GT1 Replace with CORI cart or console
Gibson, Thomas, 12/1/2020

GT3 Add slide of handpiece
Gibson, Thomas, 12/14/2020

What is Osteoarthritis?

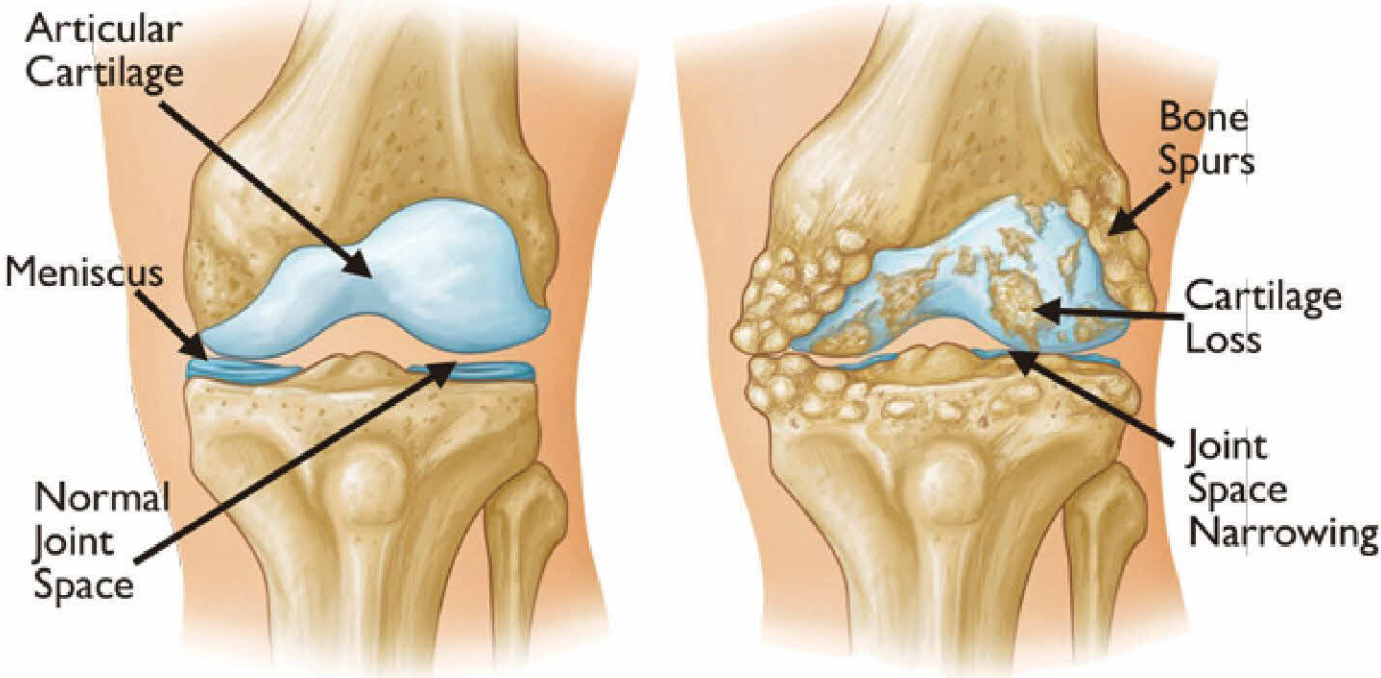


- A degenerative bone disease that causes cartilage found on healthy joints to break down¹
- The most common form of arthritis and a leading cause of disability in the U.S.²
- 45% of people will develop knee OA over their lifetime according to one study²



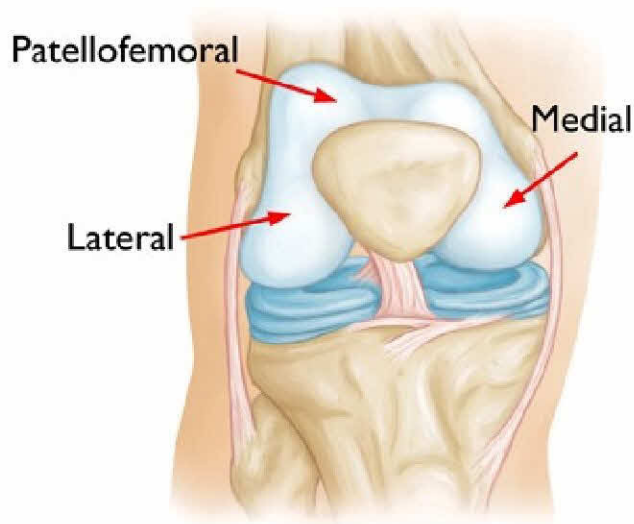
1. Arthritis of the knee, AAOS.com <http://orthoinfo.aaos.org/topic.cfm?topic=a00212>
2. Arthritis Care & Research, September 2008

Osteoarthritis



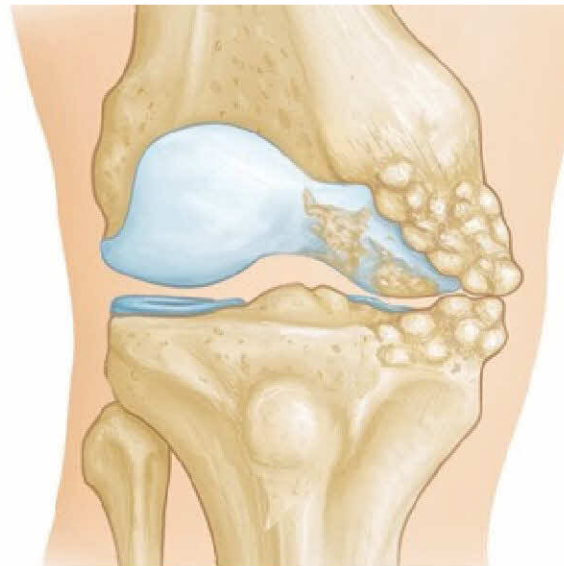
Osteoarthritis Disease Progression

Early-stage¹



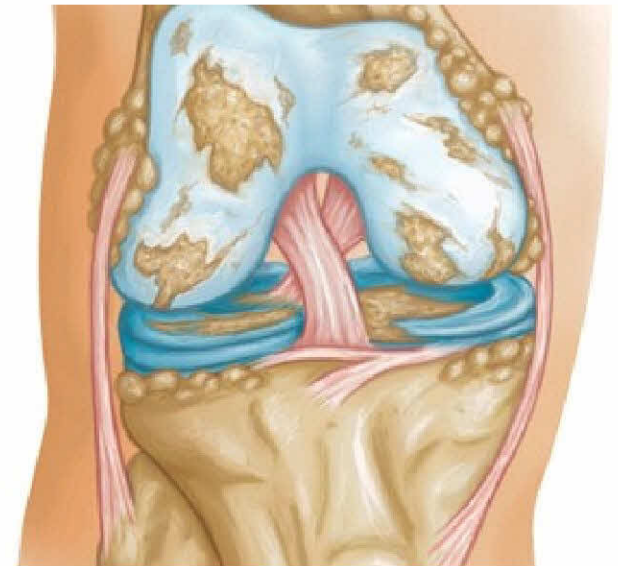
- Sports injury
- Minor defect/loss of cartilage

Mid-stage¹



- Increased pain
- Reduced mobility
- Single or bi-compartmental

Late-stage²



- Severe pain
- Walking and/or stair climbing challenging
- All compartments of the knee affected

1. Unicompartamental knee replacement, <http://orthoinfo.aaos.org/topic.cfm?topic=a00585>
2. Total knee replacement, <http://orthoinfo.aaos.org/topic.cfm?topic=a00585>

Diagnosing Osteoarthritis



Healthy Knee^{1,2}



Medial Osteoarthritis¹



Medial and Lateral
Osteoarthritis²

1. Unicompartamental knee replacement, <http://orthoinfo.aaos.org/topic.cfm?topic=a00585>
2. Total knee replacement, <http://orthoinfo.aaos.org/topic.cfm?topic=a00585>

Conservative treatment options

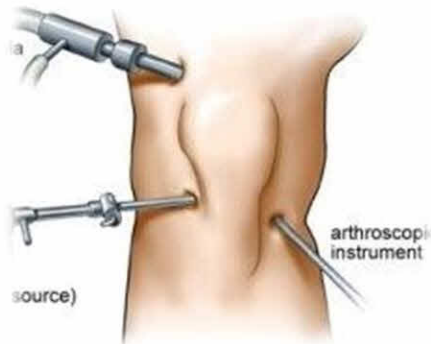


- Weight loss
- Changes in activity/lifestyle modifications
- Anti-inflammatory medication or alternative
- Cortisone injections
- Hyaluronic injections
- Braces
- Tens unit
- Stem cells



1. Arthritis of the knee, AAOS.com
<http://orthoinfo.aaos.org/topic.cfm?topic=a00212>

Surgical treatment options



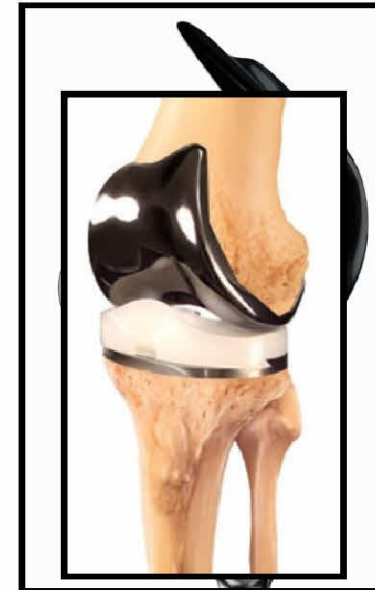
Arthroscopy

- Early stage
- Often sports related injuries



Partial knee replacement

- Early to mid stage
- 'Wear and tear' osteoarthritis affecting one compartment of the knee

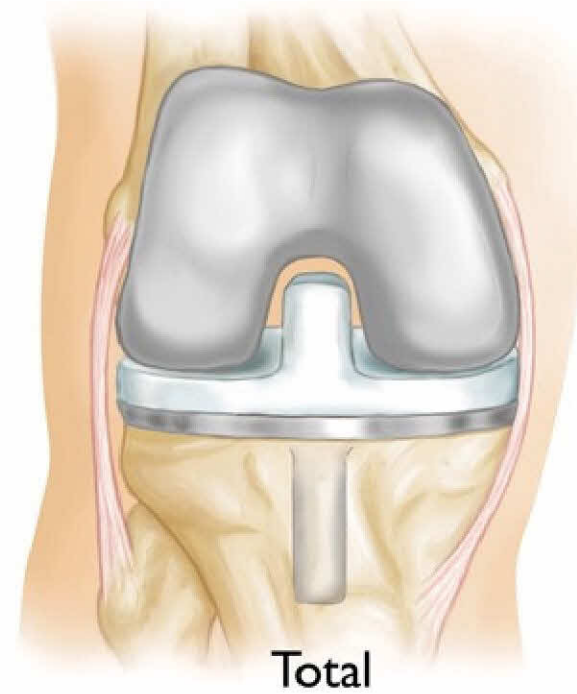
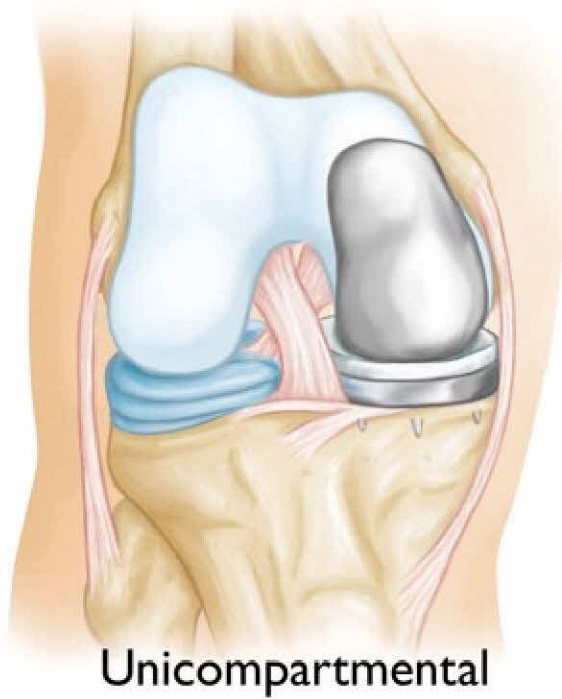


Total knee replacement

- Late stage
- Severe pain and difficulty performing daily tasks
- All compartments of the knee affected

Which one is right for you?

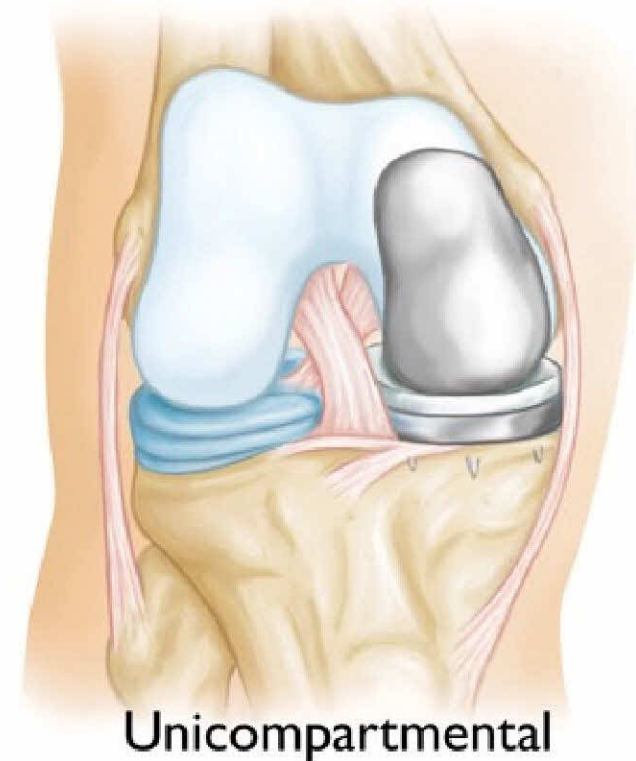
S+N



Partial knee replacement

Advantages

- According to a study **94% very satisfied vs. 81% total knee satisfaction**¹
- According to a study **95% of patients would choose to undergo the procedure again**¹
- Only replacing damaged compartment of the knee
 - **Spares healthy ligaments and tissue**
- Compared to total knee replacement, partial knee replacement means²:
 - **Less pain**
 - **Quicker recovery**
 - **More range of motion**
 - **Smaller incisions**
 - **A more normal feeling knee**



1. Von Kuedell 2012. Patient satisfaction after primary total and unicompartmental knee replacement
2. Hall et al., "Unicompartmental Knee Arthroplasty (Alias Uni-Knee): An Overview With Nursing Implications," Orthopaedic Nursing, 2004;

Total knee replacement

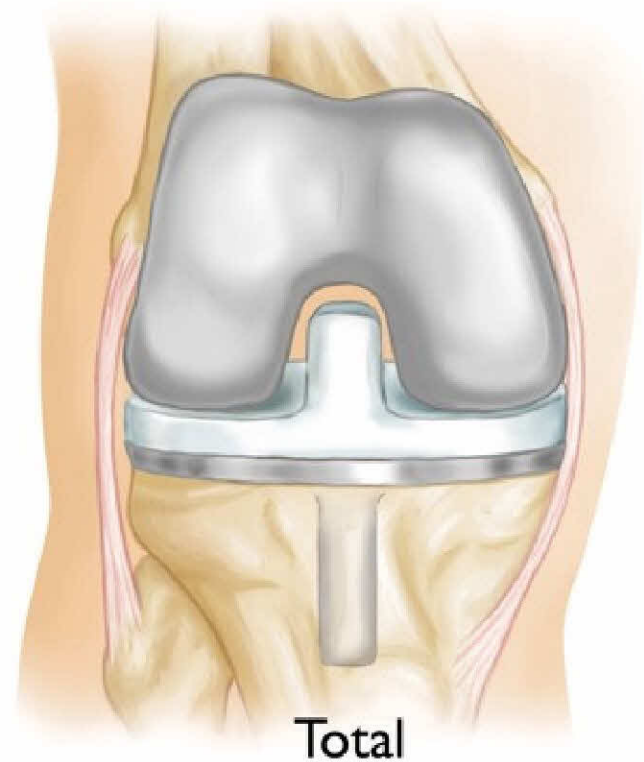


Advantages

"One of the most successful procedures in all of medicine."

- American Academy of Orthopaedic Surgeons¹

- Over 600,000 performed every year in the U.S.¹
- More than 90% experience a dramatic reduction of knee pain and a significant improvement in the ability to perform common activities of daily living¹

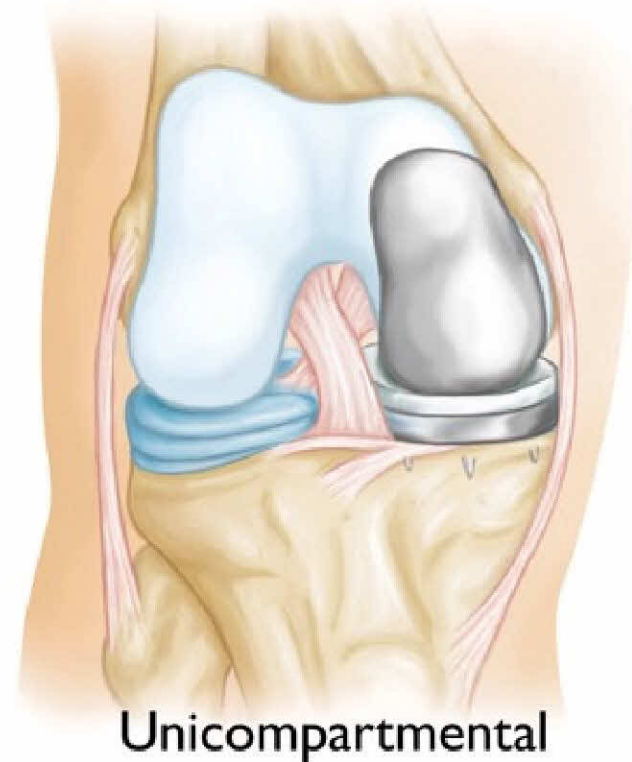


1. Total knee replacement, <http://orthoinfo.aaos.org/topic.cfm?topic=a00585>

Partial knee replacement

Limitations

- Not everyone is a candidate
- Limited patient pool
- About 20% of patients may have osteoarthritis in one of the three knee compartments¹
- Candidates must meet strict criteria
 - Non-inflammatory arthritis
 - Intact ACL
 - No lateral compartment disease
 - Grade I-III patella-femoral disease
 - Correctable varus/valgus deformity of less than 15 degrees
 - Less than 10 degrees of flexion contracture



1. Liddle 2014. Adverse outcomes after TKR and UKR replacement

Partial knee replacement



Limitations

- Considered by many to be a technically challenging procedure
- Study from the National Joint Registry for England and Wales
- 101,330 total knee replacement patients studied

Conclusion:

21% of patients met the criteria for partial knee replacement

Articles

Adverse outcomes after total and unicompartmental knee replacement in 101 330 matched patients: a study of data from the National Joint Registry for England and Wales

Alexander D Liddle, Andrew Judge, Håkan Pors, David W Murray

Summary
Background Total knee replacement (TKR) or unicompartmental knee replacement (UKR) are options for end-stage osteoarthritis. However, comparisons between the two procedures are confounded by differences in baseline characteristics of patients undergoing either procedure and by insufficient reporting of endpoints other than revision. We aimed to compare adverse outcomes for each procedure in matched patients.

Methods With propensity score techniques, we compared matched patients undergoing TKR and UKR in the National Joint Registry, for England and Wales. The National Joint Registry started collecting data in April 1, 2003, and is continuing. The last operation date in the extract of data used in our study was Aug 28, 2012. We linked data for multiple potential confounders from the National Health Service Hospital Episode Statistics database. We used regression models to compare outcomes including rates of revision, revision/reoperation, complications, readmission, mortality, and length of stay.

Findings 25 134 UKRs were matched to 75 996 TKRs on the basis of propensity score. UKRs had worse implant survival both for revision (hazard ratio [HR] 2.12, 95% CI 1.97-2.30) and for revision/reoperation (1.28, 1.31-1.44) than TKRs at 8 years. Mortality was significantly higher for TKR at all timepoints than for UKR (30 day hazard ratio 0.23, 95% CI 0.11-0.50; 8 year: 0.85, 0.79-0.92). Length of stay, complications (including thromboembolism, myocardial infarction, and stroke), and rate of readmission were all higher for TKR than for UKR.

Interpretation In decisions about which procedure to offer, the higher revision/reoperation rate of UKR than of TKR should be balanced against a lower occurrence of complications, readmission, and mortality, together with known benefits for UKR in terms of postoperative function. If 1000 patients receiving TKR received UKR instead, the result would be around one fewer death and three more reoperations in the first 4 years after surgery.

Funding Royal College of Surgeons of England and Arthritis Research UK.

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Introduction
Total knee replacement (TKR), usually undertaken for end-stage osteoarthritis, is one of the commonest surgical procedures, with more than 70 000 TKRs done every year in the UK.¹ International trends suggest that this number will rise substantially, largely because of the ageing population and an increased prevalence of risk factors, including obesity.²

TKR is a highly successful and cost-effective procedure. In terms of implant survival, more than 95% are in situ 10 years after surgery.^{3,4} However, implant survival is an imperfect measure. With this measure, patients who have died, those who undergo reoperations that are not regarded as revisions (such as detritement for infection or manipulation under anaesthesia for stiffness), and those who have poorly functioning, but unrevised, knee replacements, are all classed as successes.⁵

The proportion of TKRs that is judged successful changes with the use of different outcome measures. 90-day mortality after TKR is 0.4%,⁶ by 4 years, 3.4% of patients undergo a non-revision reoperation,⁷ 8-9% of patients have worse patient-reported outcome measures 6 months after knee replacement than they had beforehand⁸ and up to 20% are dissatisfied after TKR.⁹

A large proportion of patients who are eligible for TKR are also eligible for unicompartmental knee replacement (UKR) in which only the parts of the knee affected by osteoarthritis are replaced.¹⁰ Fewer patient reported outcomes can be obtained with UKR than with TKR, and mortality and major complications are lower after UKR than after TKR.¹¹ However, unpublished data from national registries show a significantly higher revision rate for UKR than for TKR.¹² Because revision rate has traditionally been regarded as the most important factor to determine implant choice, only 8% of knee replacements done each year in the UK are UKRs, and most knee surgeons do not do them.

As such, the use of UKR in the treatment of end-stage osteoarthritis is controversial. Fair comparison of TKR and UKR is hampered by differences in the baseline characteristics of patients being offered each procedure.

www.thelancet.com Vol 384, October 18, 2014 1407

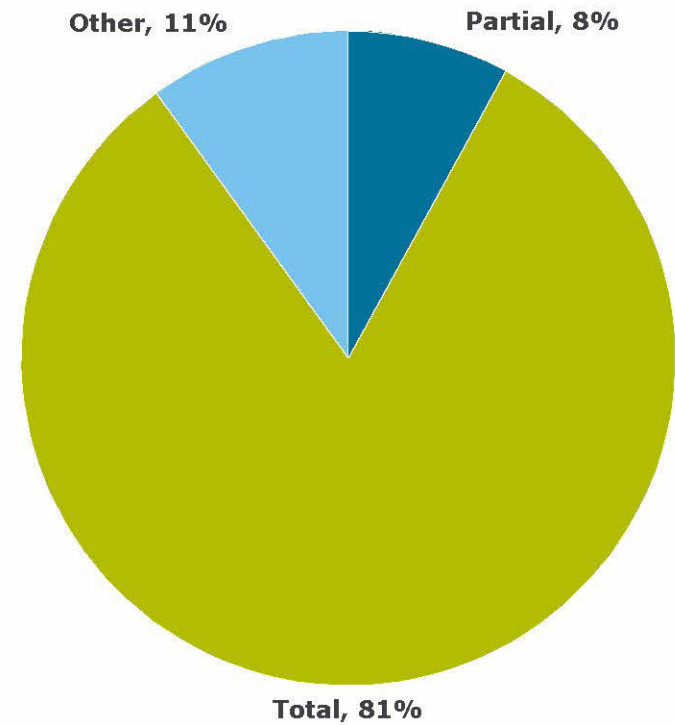
1. Liddle 2014. Adverse outcomes after TKR and UKR replacement

Partial knee replacement



Limitations

- Considered by many to be a technically challenging procedure
- Greater than 20% may be candidates¹
- Only 8% of knee replacements in the U.S.² are partial knee replacements



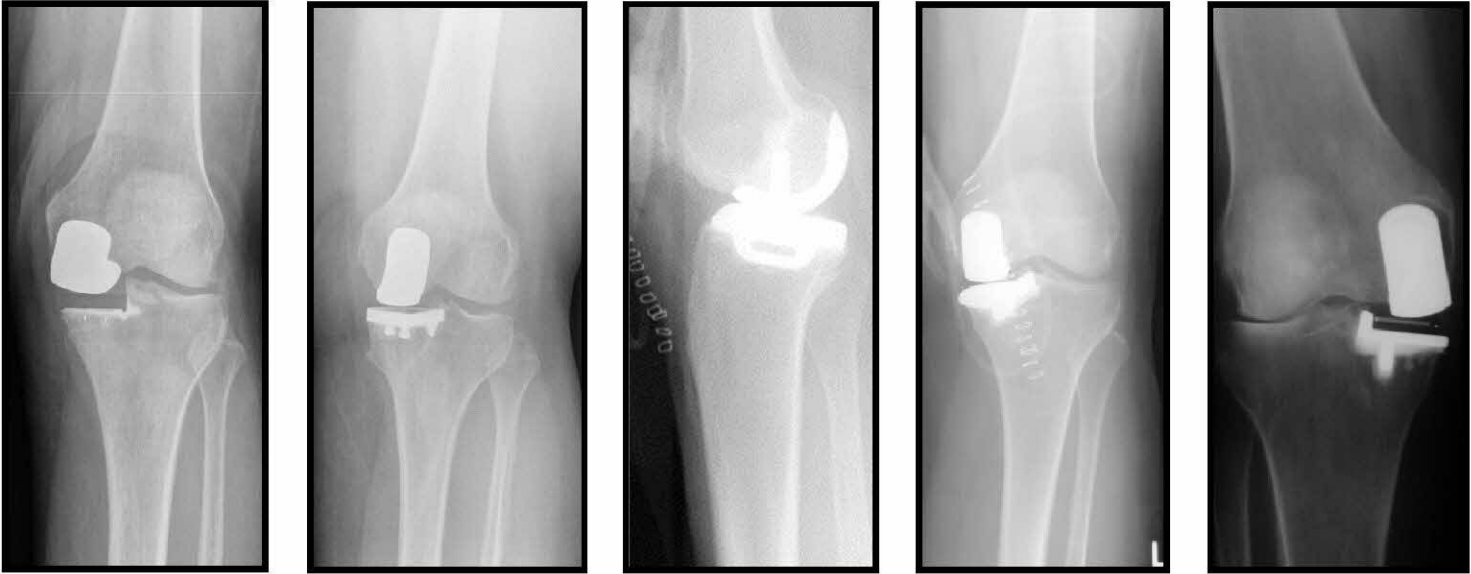
1. Liddle 2014. Adverse outcomes after TKR and UKR replacement
2. Large joint reconstruction U.S. Market, 2012, Millennium research group, page 57

Partial knee replacement



The accuracy of implant positioning matters

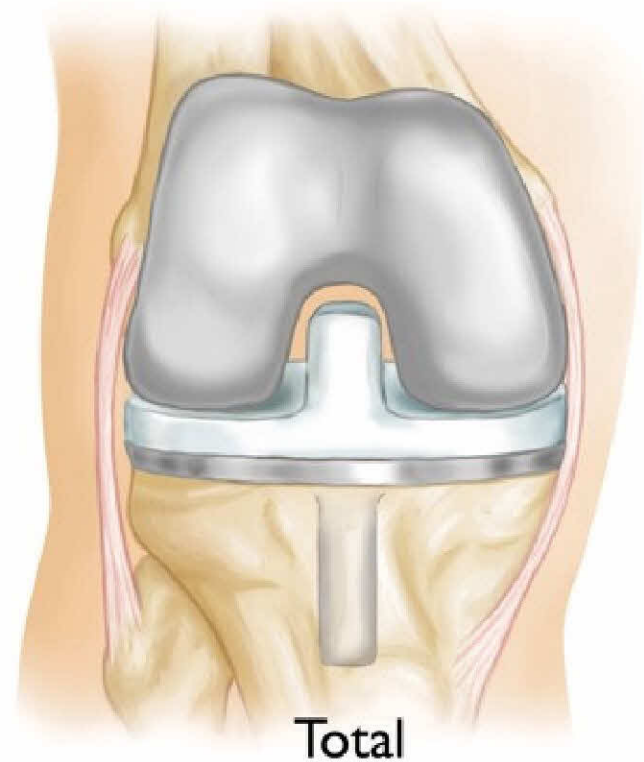
When things go wrong it can be easy to spot



Total knee replacement

Limitations

- It's a great procedure, but is there room for improvement?
- Study on early revision - Sharkey et.al. Insall Award Paper 2002
 - 56% of Revisions done within 2 years of total knee procedure
- Reasons for the Early Failures:
 - Fixation failure (17%)
 - Instability (21%)
 - Malalignment (12%)



A robotic-assisted solution



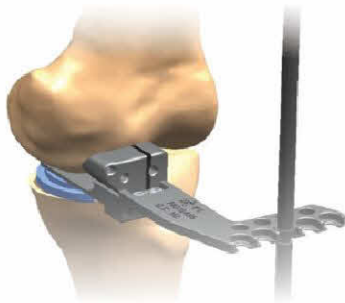
- Robotic-assistance provides accuracy that can help improve the function, feel and potential longevity of the knee implant.¹
- Robotic-assistance is now used in 15% to 20% of partial knee replacement procedures in the U.S.¹
- Robotic-assistance is now available for total knee replacement



1. Lonner, Jess, Moretti, Vince, "The Evolution of Image-Free Robotic Assistance in Unicompartmental Knee Arthroplasty.", *The American Journal of Orthopedics*, May/June 2016, 249-254. Accessed June 7, 2016

Traditional instrumentation

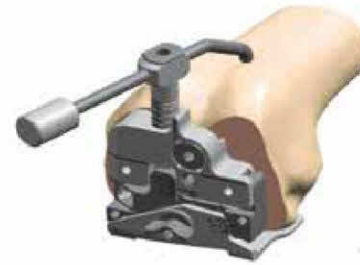
- Mechanical guides, jigs, feel



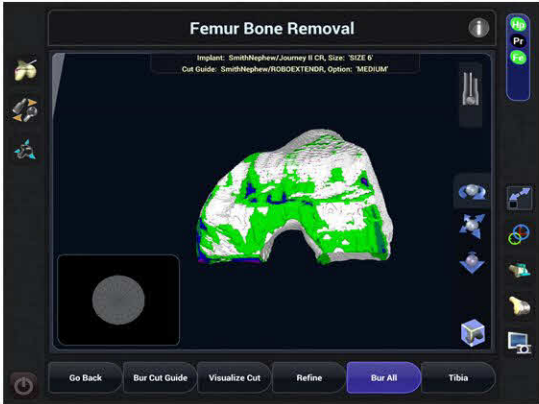
Thigh bone (femur) guide



Shin bone (fibial) guide



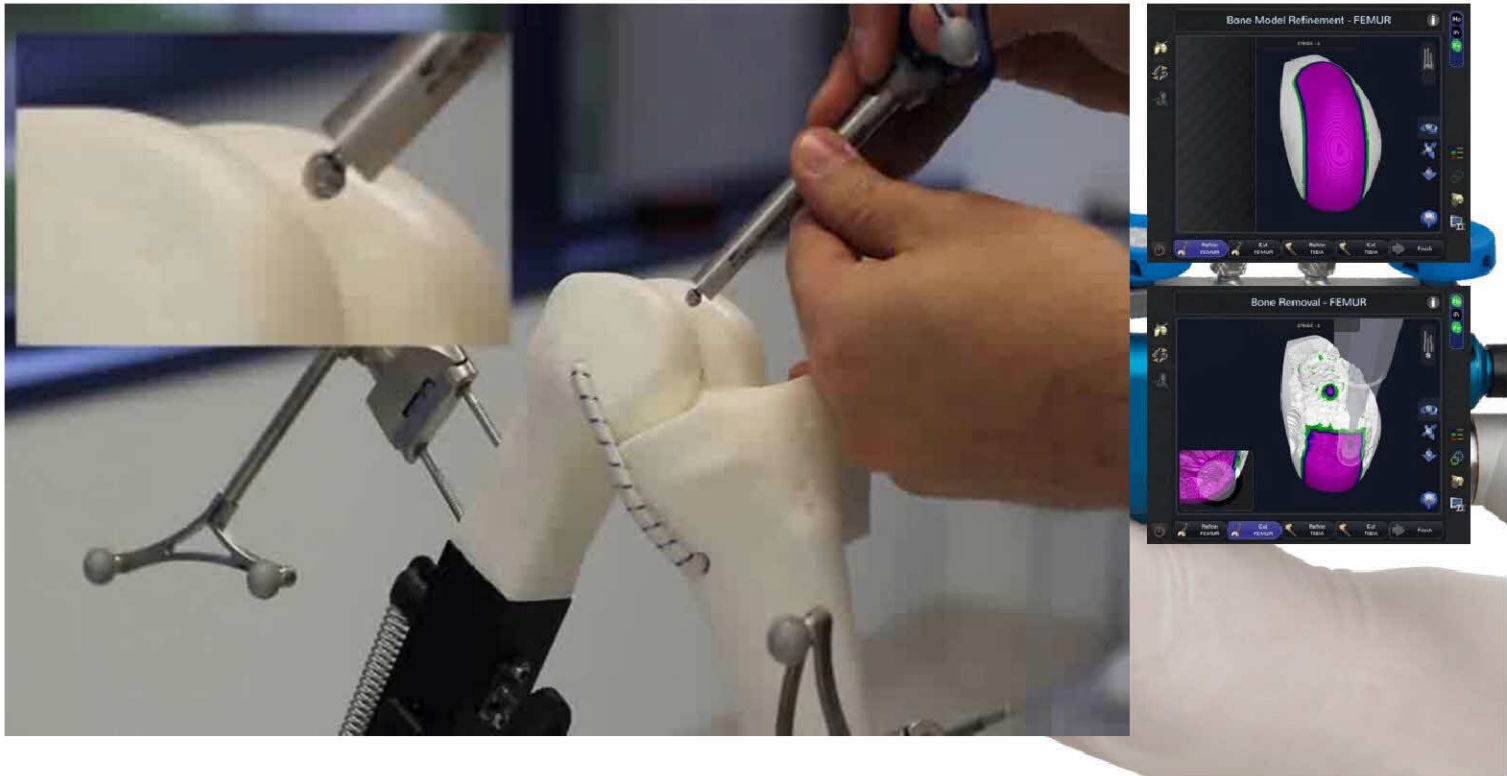
- Computer and robotic-assistance to achieve accurate and individualized results



The CORI^o handpiece



- A robotic-assisted high-speed bur ensures the surgeon only removes bone within the surgeon defined plan



CT-free technology



BCBS of CA Coverage Policy Update (April 2016)

Any of the following technologies for knee replacement are considered **investigational**:

- Bicompartmental knee replacement, including bi-unicompartmental
- Customized knee replacement, including **any** of the following:
 - Customized templates, and/or instrumentation
 - Customized knee implant
 - "Gender specific" implant
 - Pre-operative imaging studies (e.g., CT scans, MRI) associated with the customization and/or utilized as part of intraoperative navigation (e.g., MAKOplasty)
- Focal resurfacing of a single knee joint defect (e.g., HemiCAP™, UniCAP™)
- Minimally invasive approaches to knee arthroplasty

Harvard Pilgrim Coverage Policy Update (July 2015)

Exclusions:

HPHC does not cover:

- ❖ Customized knee replacement, including imaging studies (e.g., CT scans, MRI) associated with the customization, patient-specific template components and/or patient-specific instrumentation (e.g., MAKOplasty) derived from patient imaging data, customized knee prosthesis, gender specific prosthesis



Cigna Coverage Policy Update (June 2015)

Cigna does not cover ANY of the following because each is considered experimental, investigational or unproven:

- bicompartmental knee replacement, including bi-unicompartmental
- customized knee replacement, including ANY of the following:
 - pre-operative imaging studies (e.g., CT scans, MRI) associated with the customization and/or utilized as part of intraoperative navigation (e.g., MAKOplasty)
 - customized templates, and/or instrumentation
 - customized knee implant
 - gender specific implant
- minimally invasive approaches to knee arthroplasty
- unicdylar interpositional spacer (e.g., UniSpacer™)
- focal resurfacing of a single knee joint defect (e.g., HemiCAP™, UniCAP™)

Robotics designed to precisely align implants



- Poor alignment will lead to uneven wear
- Tire balancing analogy:
 - Mechanics now use advanced, computer-assisted tools to ensure our tires are properly balanced



1. Ranger products, Tire balancing

GT4

CORI [◇] robotic-assisted partial knee replacement

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Smith+Nephew

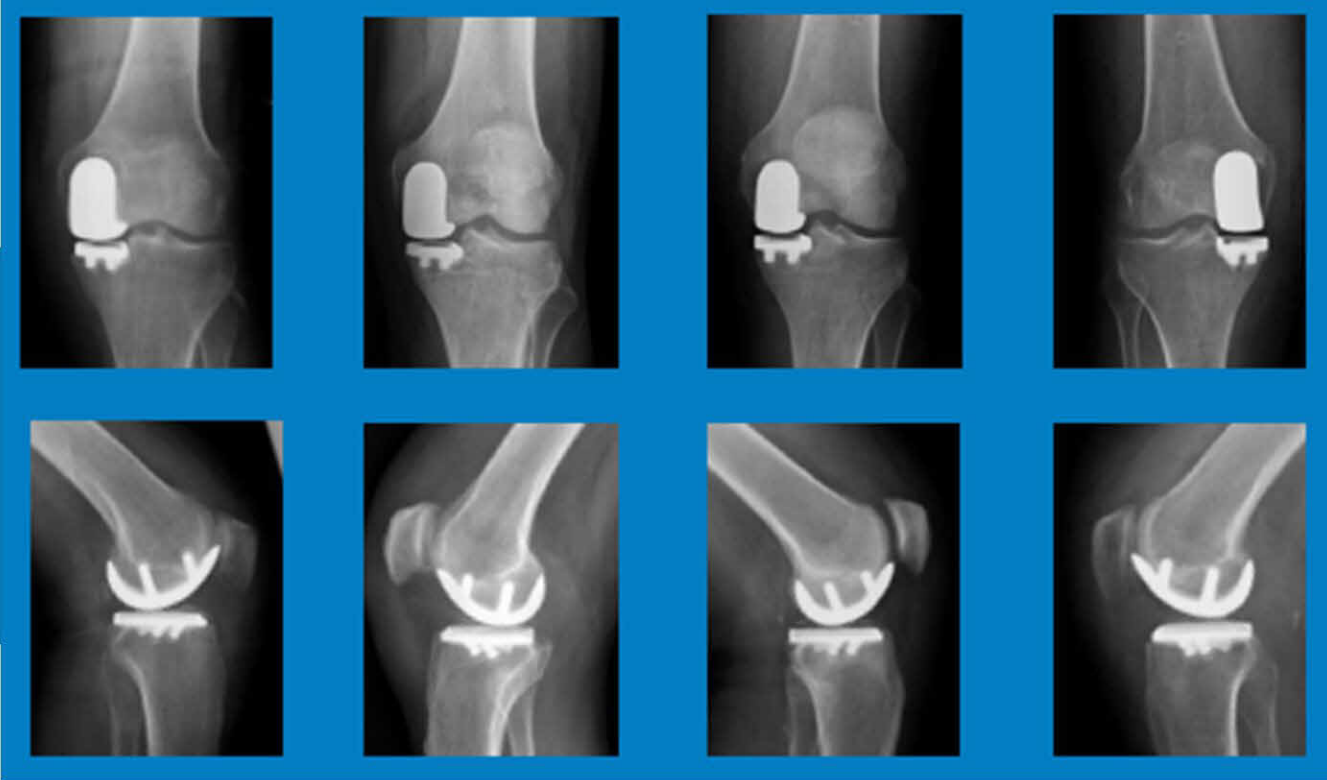
CORI [◇]
Surgical System

RI.KNEE ROBOTICS
Unicompartmental Knee Arthroplasty

Slide 23

GT4 Add final ROM info slide
Gibson, Thomas, 12/14/2020

CORI[◊] partial knee radiographic outcomes



Individual results will vary. These results are not typical of every robotic-assisted partial knee replacement procedure.

CORI[◇] robotic-assisted total knee replacement



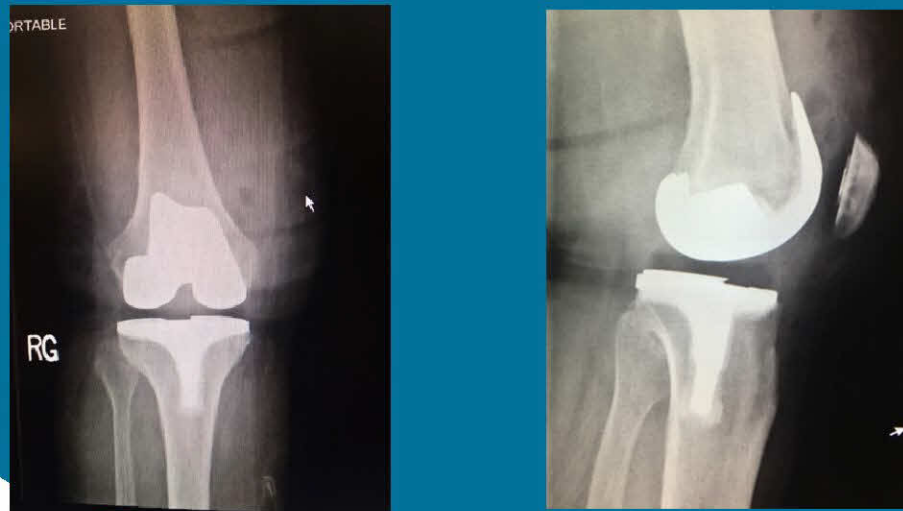
Smith+Nephew

CORI[◇]
Surgical System

RI.KNEE ROBOTICS
Total Knee Arthroplasty

CORI[®] total knee radiographic outcomes

S+N



Individual results will vary. These results are not typical of every robotic-assisted partial knee replacement procedure.

Common Questions



Who would be a good candidate for a partial knee procedure?

- Although the best treatment for each patient must be determined individually, typical patients share the following characteristics:

Knee pain with activity on the inner knee

Start up knee pain or stiffness when activities are initiated from a sitting position

Failure to respond to non-surgical treatment such as rest, weight loss, physical therapy and non-steroidal anti-inflammatory medication

Common Questions



Who would be a good candidate for a total knee procedure?

- Although the best treatment for each patient must be determined individually, typical patients share the following characteristics:

Severe knee pain or stiffness that limits your everyday activities

Moderate or severe knee pain while resting

Chronic knee inflammation and swelling that does not improve with rest or medications

Failure to substantially improve with other treatments such as anti-inflammatory medications, cortisone injections, lubricating injections, physical therapy, or other surgeries

Common Questions



How long can I expect the implant used in a procedure to last?

- Alignment and positioning are very important factors affecting the life expectancy of an implant.
- **The goal of computer-assisted and robotic-assisted procedure is to achieve the best alignment and positioning for your implant to help it last as long as possible.**

1. Lonner, Jess, Moretti, Vince, "The Evolution of Image-Free Robotic Assistance in Unicompartmental Knee Arthroplasty.", The American Journal of Orthopedics, May/June 2016, 249-254. Accessed June 7, 2016

Closing Points



What are the benefits of this the CORI System?

- Robotic assisted technology for accurate and individualized implant planning
- CT free technology
- Can assist in partial and total knee replacement

Thank you for coming



- Please return completed comment cards to host upon exiting

Questions?