Focal Cartilage Resurfacing of the Knee with Metallic and Polyethylene Implants: Closing the Treatment Gap Between Cell and Tissue Based Therapies and Knee Arthroplasty

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Abstract: Articular cartilage lesions, osteochondral defects, and osteoarthritis of the knee represent a considerable source of pain and dysfunction for patients globally. Current surgical treatment options include a variety of cell and tissue-based treatments as well as unicompartmental and total knee arthroplasty. Unfortunately, current cell and tissue-based preservation strategies for treating cartilage lesions are dependent on variable factors including unpredictable biologic integration, demanding technical expertise, expensive cadaveric donor sources, and extensive rehabilitation requirements. Although outcomes of knee arthroplasty are more predictable, these procedures sacrifice adjacent healthy tissue unnecessarily by their design. As such, a gap in the treatment spectrum of knee cartilage lesions exists between these two extremes. Selective cartilage resurfacing systems, such as the OvertureTI Knee Resurfacing System®, offer a strategic solution for treatment of cartilage lesions by addressing structural cartilage abnormalities with a durable bipolar implant while preserving healthy surrounding tissue. This white paper will highlight the current challenges in cartilage repair encountered by knee surgeons worldwide and discuss how selective resurfacing of the knee represents a breakthrough treatment in the standard of treatment for these conditions.

Introduction: The annual number of cartilage restoration surgeries performed annually exceeds 300,000, with some single procedures such as chondrocyte implantation reaching costs as high as $83,073 due to multi-stage surgeries, laboratory processing, and associated episode of care and societal costs.[1,2] This trend has been driven by an increased global incidence of osteoarthritis and cartilage defects among an increasing range of demographics. Indeed, although osteoarthritis has been traditionally thought of as a musculoskeletal condition affecting older populations, recent population-based analyses suggest otherwise. According to a recent meta-analysis, 16% of people aged 15 and older globally have knee osteoarthritis (OA), while 30.4% of people diagnosed with osteoarthritis in one study reported being diagnosed before age 45.[3] Treatment of cartilage defects when identified is critical as even small, focused areas of damaged cartilage if left untreated can progress in size and lead to extensive cartilage loss over time.[4]

Despite an increased recognition surrounding the prompt diagnosis and treatment of cartilage lesions of the knee, current surgical options for treatment of isolated cartilage defects continue to present significant challenges for patients and surgeons in terms of cost and complexity.[5] Importantly, these limitations hinder widespread adoption and accessibility of treatments, which may affect patient outcomes and increase the burden on healthcare systems.[5] Addressing these challenges is critical to improving the accessibility, affordability, and efficacy of knee cartilage treatments, ultimately enhancing patient outcomes, quality of care, and reducing the burden on healthcare systems.

Limitations Inherent in Current Approaches to Cartilage Treatment Preclude Reproducible Outcomes

Cost and inaccessibility are significant limitations of current methods of cartilage repair.[6] Specifically, the procurement, processing, and storage of biologic allografts are expensive and prone to degradation. Donor tissue must be meticulously screened and prepared, which adds to the overall cost of the surgery and episode of care. Furthermore, certain procedures, such as autologous chondrocyte implantation, require the multi-step process of cell harvesting, culturing, re-implantation, and the need for a controlled laboratory environment (Figure 1); as such, multiple surgical procedures are inconvenient for patients and increases healthcare costs.[6] Indeed, the substantial expenses involved in these treatments make them inaccessible to many patients, particularly those without comprehensive insurance coverage or financial means.

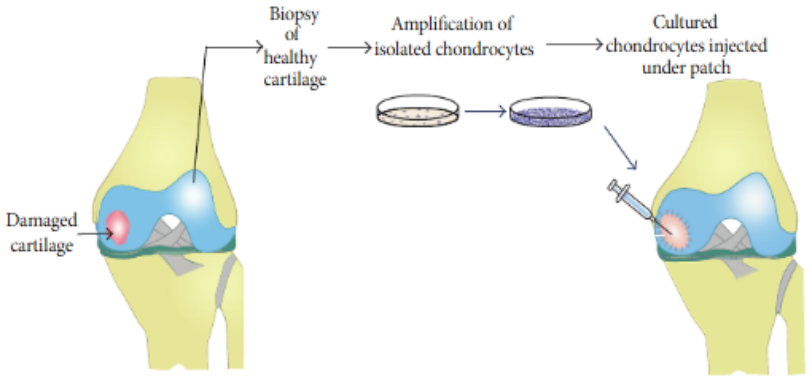


Figure1: Procedural steps of autologous chondrocyte implantation require two separate surgeries. *Image source: Bauge, Catherine & Boumediene, Karim. (2015). Use of Adult Stem Cells for Cartilage Tissue Engineering: Current Status and Future Developments. Stem cell International. 10.1155/2015/438026.*

Donor availability is another challenge with current allograft methods for cartilage injuries.[7] Finding suitable donor tissue can be difficult, leading to long waiting times for patients. The supply of high-quality allografts is limited. Not only can allografts be challenging to procure but require considerable technical expertise as the procedures are intricate and require specialized surgical skills and equipment. These factors also increase the cost of the operation and the complexity of completing the procedure.[7]

With any biologic treatment, there is a risk of incompatibility.[8] In this context, the risk of graft rejection and issues with the integration of the transplanted tissue into the patient's knee can potentially increase procedural morbidity. This, in turn, can necessitate additional treatments and prolong recovery. Rehabilitation is another important limitation associated with current methods of cartilage treatment and is generally both arduous and burdensome for the patient.[6,7] Extensive rehabilitation and follow-up care are necessary to ensure successful integration of the donor cartilage, but also increase the overall treatment and time burden. Some treatments, such as chondrocyte implantation, require several weeks of cell culturing before re-implantation can occur, leading to prolonged treatment periods and delays in treatment.[6,8]

Focal Cartilage Resurfacing Represents a Novel Approach to Cartilage Treatment Created to Overcome Existing Challenges

For patients with cartilage defects, existing treatments including knee arthroscopy, autograft cartilage transfer, allograft cartilage transplant, and cartilage cell implantation result in variable outcomes due to inherent biologic, technical, and compliance challenges as described above.[9] These challenges limit the overall efficacy of existing treatments by introducing treatment variability and healthcare inequities concerning access.[9] Therefore, a solution that allows for focal cartilage treatment similar to cell-based treatments, but that is durable like metallic knee arthroplasty, could enhance treatment for this patient population. Indeed, early studies have shown more favorable and durable results with the use of focal, metallic implants over cell and tissue-based treatment options.[10-12] Partial and total knee arthroplasty represent the other end of the spectrum, though possess the disadvantage of removing healthy bone and cartilage around the defects.[13] Therefore, until recently, a gap in treatment of cartilage injuries (Figure 2) has existed between cell and tissue-based treatment and knee arthroplasty, despite the demand for cartilage repair continuing to increase.

Figure 2: Treatment gap for cartilage injuries. The gap consists of patient who are not candidates for cell/tissue-based therapies, Total Knee or Unicondylar Knee Replacements.

The OvertureTi Knee Resurfacing System is an FDA cleared implant system composed of bipolar femoral and tibial implants that are intended to be used in the partial replacement of the articular surfaces of the knee. These implants are designed with sizing options that allow the surgeon to replace only the diseased or damaged region of the joint while preserving healthy surrounding cartilage and meniscus - a new technique called Focalplasty® (Figure 3).

Technical Overview: The OvertureTi Knee Resurfacing System uses novel technological advancements in implant design to create components that provide a strategic advantage for cartilage surgery. The resurfacing system consists of a bipolar implant design which allows for a low-profile construct that is inherently bone sparing and meniscus sparing to allow for retention of adjacent healthy tissues. Both components (femoral and tibial) feature biocompatible, 3D-printed, porous titanium baseplates that mimic the natural structure of bone.

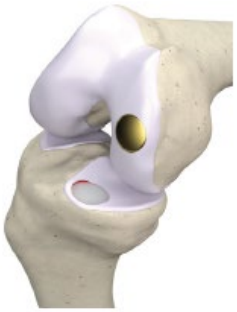


Figure 3: Bipolar femoral and tibial implants.

Femoral Component Technology and Specifications

The OvertureTi Femoral Implants® (Figures 4 & 5) have several unique features that facilitate the ability to perform focal resurfacing and overcome challenges inherent in cell and tissue-based therapies. The porous titanium baseplate facilitates implant stability and mitigates concerns of delamination, resorption, and biologic rejection associated with biologic cartilage options such as osteochondral allograft (OCA). The Titanium Nitride (TiN) ceramic coating is nickel free and minimizes wear rates, promoting implant longevity. Barbed pegs and anti-rotation spikes on the titanium baseplates provide additional fixation and stability within the prepared bone, minimizing the need for large amounts of cement. Surgical complexity of addressing large or adjacent cartilage lesions with technically challenging approaches, such as the Snowman technique for OCA, is eliminated by offering a large selection of shape and size offerings to accommodate various cartilage defect morphologies. Femoral implants are offered in oblong and round configurations. The oblong femoral implants are offered in lengths ranging 30-40mm and widths ranging 17.5-22.5mm, and the round femoral implants are offered in diameters ranging 17.5-25mm

Figure 4: Round femoral implant.

Figure 5: Oblong femoral implant.

Tibial Component Technology and Specifications

The features of the OvertureTi Tibial Implants® also offer several distinct advantages (Figure 6). The tibial implant is constructed with a Vitamin E infused, ultra-high-molecular-weight polyethylene bearing surface – the same polyethylene utilized in total joint arthroplasty with minimal concerns for oxidation, wear and osteolysis at over 20-year follow-up. Unique to the OvertureTi Tibial Implant is the 10° angled design of the polyethylene surface, which reduces the overall stress experienced on the soft tissues and does not interfere with the femoral condyles during insertion. Like the femoral component, anti-rotation spikes are present on the porous tibial baseplate, increasing implant stability. The tibial implants are offered in diameters ranging from 17.5-22.5mm.

Figure 6: Tibial Implant.

Overall, the intuitive design and selection of implant options to accommodate a wide range of cartilage lesion morphologies allow for a low learning curve to achieve surgical consistency and reproducibility. The unique combination of technologic features at the structural level designed specifically for the OvertureTi Knee Resurfacing System results in an implant system that is durable and minimally disruptive to surrounding structures. The limited number of necessary trays and availability of multiple implant options contribute to the scalability of the device and minimal use of hospital resources.

Key Features: The overall goal of the OvertureTi Knee Resurfacing System is to provide surgeons with a previously unavailable strategy to treat cartilage lesions and early osteoarthritis with a simplified, single-stage surgery. When compared to current knee cartilage and osteoarthritis solutions, the OvertureTi Resurfacing Systems offers the following advantages:

	OvertureTi Resurfacing System	Cell-based therapy	Tissue-based therapy	Arthroplasty
Preservation of healthy, native cartilage	✅	🚫	🚫	🚫
Cost-effective	✅	🚫	🚫	✅
Single-stage procedure	✅	🚫	✅	✅
Reproducible outcomes	✅	🚫	🚫	✅
Low technical complexity	✅	✅	🚫	🚫
Reliable fixation	✅	🚫	🚫	✅

Cell-based therapy: autologous chondrocyte implantation (ACI), matrix-assisted ACI (MACI)

Technology that Benefits Both Patients and Healthcare Providers

The advantages inherent in the OvertureTi Knee Resurfacing System benefit both patients and providers and supports all provider channels with the goal to drive better patient outcomes. As it pertains to providers, this off-the-shelf implant system now offers a solution for focal resurfacing of cartilage lesions in patients who have failed conservative management. Whether performing 10 or 100 cartilage surgeries per year, the simplified technique for utilizing this implant system allows for utilization across wide provider experience levels and hospital systems. This system can also be mixed with other cartilage techniques if necessary and does not preclude concomitant surgical procedures. The implant size and single set of instruments do not require significant storage space and decreases sterile processing time.

For patients, selective resurfacing also offers several important benefits. Unlike most cell- and tissue-based procedures, patients are allowed to be weight bearing as tolerated after the procedure, simplifying rehabilitation and return to activities of daily living. Surveillance of the implant, if necessary, can be performed with radiographs, unlike cell and tissue-based therapies that require costly advanced imaging or a second arthroscopic procedure. In comparison to arthroplasty, the selective resurfacing and retention of healthy tissues as well as limited surgical exposure limits postoperative pain allowing for quick recovery and consistent same-day discharge.

Clinical Applications: Limiting the total number of surgical trays and associated processing is not only cost-effective but allows for clinical use of the OvertureTi Knee Resurfacing System across multiple healthcare settings. Indeed, minimal storage requirements and processing allows for this implant system to be used not only in large academic hospital centers, but also ambulatory surgical centers and smaller community hospitals.

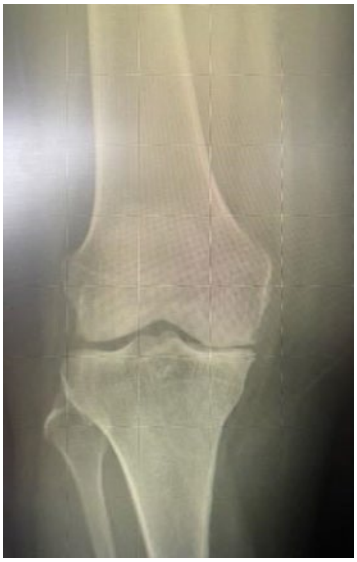
In addition to the financial benefits pertaining to hospital processing and service-lines, the OvertureTi Knee Resurfacing System confers important clinical improvements in patients with a wide range of demographic profiles and activity levels.

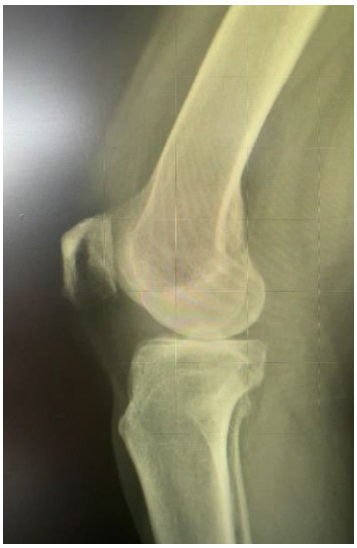
Typical Patient Profile:

- Age 35-60 years of age
- Knee within 5° of full extension
- Knee demonstrates at least 120° of flexion
- Normal stability examination
- 50%$^{+}$ meniscal volume
- Weight-bearing line falls within the central 75% of the affected compartment
- Preserved joint space in affected compartment
- Preserved joint space in remaining compartments
- Patellar mobility of at least 10mm medially/laterally
- <3mm pseudo-laxity in affected compartment with coronal plane stability testing
- Focal articular cartilage loss-thinning in affected compartment (femur, tibia)

The following case study highlights a patient with grade IV Chondral Lesions of the Medial Femoral Condyle and Medial Tibial Plateau as performed by Dr. Oscar Vazquez from Summit Health Orthopedics and Sports Medicine in Hackensack, New Jersey. This is one of many examples of the clinical efficacy associated with the use of this implant system.

Pre-op





Pre-op Plan

With the medial compartment showing focal, sclerotic degenerative changes, Dr. Vazquez decided to use the OvertureTi Knee Resurfacing System to target the diseased cartilage area while leaving the surrounding cartilage and soft tissues intact. This will be a less invasive approach than a Unicondylar or Total Knee arthroplasty allowing the patient to maintain her healthy cartilage and experience potentially quicker recovery.

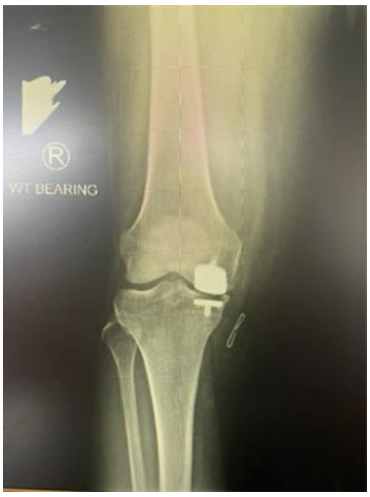
Case Presentation

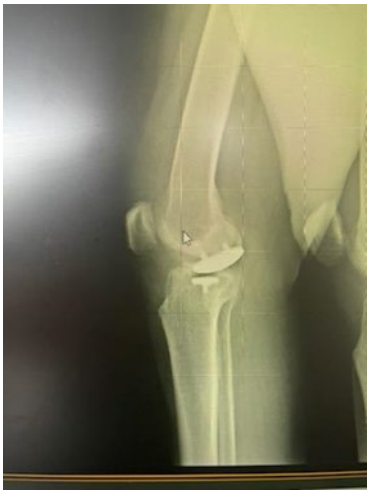
Patient is a 62 y.o. female with a long history of right knee pain over the medial compartment. The patient had a right knee arthroscopy 2 years prior, which showed early degenerative changes in the medial compartment and a medial meniscus tear. A partial medial meniscectomy was performed. The patient was treated conservatively over the next 2 years with cortisone injections, Hyaluronic Acid injections, and physical therapy. Pre-operative MRI of the right knee showed a low-grade, complex tear of the posterior horn of the medial meniscus. Preoperative AP and Lateral x-rays of the knee showed medial compartment narrowing with focal, sclerotic changes of the medial femoral condyle and medial tibial plateau.

Operative Findings and Approach

A diagnostic arthroscopy showed medial compartment grade IV changes on the femur and tibia which had exacerbated since the arthroscopy completed 2 years prior. There was a complex tear of the medial meniscus. ~30% of the meniscus was removed with a biter and shaver. A parapatellar, quad-splitting approach was used. The medial meniscus was tagged with two 0 FiberLinks. The meniscus was then released. A 20mm x 35mm oblong femoral sizer fit well over the femoral cartilage defect and proceeded with the technique for a 20mm x 35mm Oblong OvertureTi Femoral implant. Dr. Vazquez then turned his attention to the tibia and after trialing with different sizers, the 17.5mm fit well. He proceeded with the technique for the 17.5mm OvertureTi Tibial implant. Bone cement was placed into the peg holes previously drilled for the femur and tibia. The tibial component was implanted first then the femoral component in excellent position. Both implants were inset ~0.5mm from the surrounding cartilage surface. After copious irrigation, the meniscus was repaired with two 2.8mm Swivelocks anteriorly and Dr. Vazquez used 2-0 FiberWire to sew it to the bone and soft tissues.

Post-op





Follow-up

At 2-month follow-up, the patient is walking without any assistive devices. She continues to progress with physical therapy. Her range of motion is 0 to 120. She states that her pain is significantly improved from preoperative status. Her skin incisions are well healed. Her x-rays show the implants are well placed without any evidence of subsidence.

Discussion

Dr. Vazquez wants to get the best clinical outcome by preserving as much of the patient's native anatomy as possible. The OvertureTi Knee Resurfacing System allows him to specifically address the area of cartilage and bone disease that is affected. By preserving as much of the soft tissue as possible, he can theoretically provide a more natural feeling knee. This system allows him to address osteochondral defects in the middle-aged population. He can address the patient whose disease does not necessitate unicompartmental or total knee arthroplasty but is beyond the help of arthroscopic techniques alone. With the OvertureTi Knee Resurfacing System, Dr. Vazquez can address isolated femoral and tibial lesions easily and effectively.

Conclusion: The OvertureTi Knee Resurfacing System is a comprehensive surgical solution for focal cartilage injuries of the knee that respects surrounding anatomy and empowers knee surgeons to perform selective cartilage repair surgery. Overture is addressing current cartilage challenges by creating a more convenient approach to treating cartilage lesions that are safe, effective, and fulfills a gap in the spectrum of solutions for cartilage repair. Overture's proprietary technology offers the convenience of off-the-shelf implant availability, thereby avoiding the limitations of biologic resurfacing techniques, while allowing for minimally invasive treatment.

For more information about Overture's Resurfacing Solution visit: https://overtureortho.com/products

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