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Operative Techniques in

Sports Medicine

Next-Generation Cartilage Repair and the Prearthroplasty Patient Prearthroplasty Artificial Implants Part A: BioPoly

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Focal resurfacing implants for the treatment of symptomatic chondral lesions in the knee have gained popularity in recent years, as surgeons explore potential solutions for challenging conditions in young active patients. Here, we provide an overview of the BioPoly resurfacing implant, a novel self-lubricating device with characteristics similar to synthetic cartilage. The basic science of the product, patient selection, surgical technique, and early outcome data will be discussed.

KEYWORDS BioPoly, focal cartilage defect, resurfacing arthroplasty, non biological

Introduction

Focal full thickness articular cartilage and osteochondral defects frequently result in severe pain and functional impairment.[1] Despite a limited defect size the symptoms suffered by these patients can match those with osteoarthritis who are waiting for total knee arthroplasty.[1] Focal chondral lesions are of high prevalence in the young adult population and if left untreated these lesions will likely progress to osteoarthritis.[2,3]

In younger, active patients, biological treatments such as debridement, microfracture, autologous matrix induced chondrogenesis, osteochondral autograft/allograft, autologous chondrocyte implantation, and matrix-induced autologous chondrocyte implantation have shown some good results. However, there have been inconsistencies and with increasing age or when used after failure of previous biological treatments the benefits decrease, with sometimes minimal pain relief or functional improvement.[4] While biological treatments are appropriate for many younger patients, they may require multiply staged procedures, long periods of rehabilitation or reduced weight-bearing, all which make they unsuitable for the older patient who wishes to make a quick return to full activity.

Contained, focal defects do not lend themselves to arthroplasty because the risk of requiring revision surgery is highest in patients less than 50 years. In this patient population, focal nonbiological resurfacing implants can be a suitable option to delay or eliminate the need for arthroplasty. They allow a quick return to full activity and can achieve excellent success rates with similar clinical outcomes to biological treatments.[5]

The BioPoly RS partial resurfacing knee system (Fort Wayne, IN) is a biosynthetic implant with an articulating surface that is a micro composite of hyaluronic acid (HA) and ultra-high molecular weight polyethylene (UHMWPE) forming a hydrophilic polymer. The material was developed in the early 2000s at Colorado State University and has been implanted clinically since 2012. Currently 4 product lines are available—knee, patella, trochlear, and great toe. It is designed as an early intervention and treatment for patients with cartilage lesions that is bone preserving and less dependent on patient biology.

Basic Science

Advances in UHMWPE over the years have included modifications to the bulk material or surface structure to improve its wear characteristics without sacrificing unacceptable

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Conflict of Interest: The authors report no conflict of interest.

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https://doi.org/10.1016/j.otsm.2022.150964

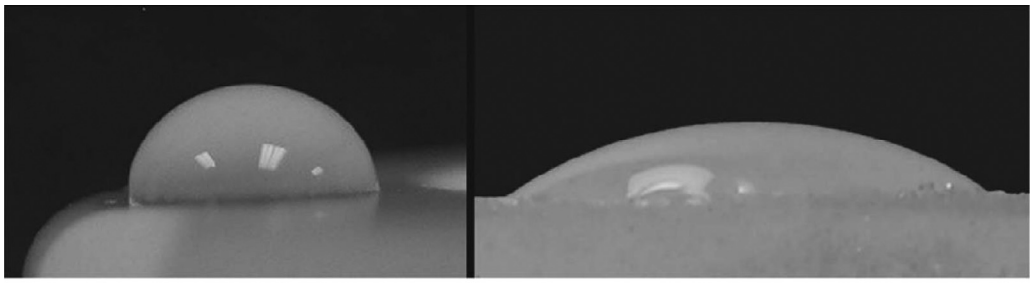

Figure 1 Photographs showing a water droplet on ultra-high molecular weight polyethylene (A) and on BioPoly material (B).

amounts of mechanical properties. However, its surface chemistry and extreme hydrophobicity contrast with the hydrophilic articular cartilage in a natural joint. It is the interaction of articular cartilage and synovial fluid that plays a key role in the very low friction and wear of synovial joints. Therefore, alterations in the surface chemistry of UHMWPE through the addition of HA were made.[6]

HA is a biologically active glycosaminoglycan present in the extracellular matrix of articular cartilage and on most human tissue surfaces. It can impart biocompatibility and lubrication to the surface of hydrophobic, synthetic biomaterials and has been used to coat various devices, such as vascular grafts and contact lenses. In its hydrated state, HA can bear compressive loads and contributes to the hydrodynamic properties of articular cartilage. Studies have demonstrated that the addition of HA to UHMWPE enhances surface lubrication and improves wear resistance.[7]

BioPoly RS is a microcomposite of cross-linked HA and UHMWPE forming a hydrophilic polymer. It is manufactured by incorporating HA into UHMWPE and cross-linking in situ to create the raw material. Implants are then direct compression molded from the material so that the final state is fully consolidated BioPoly. The microcomposite is locked onto a titanium alloy (Ti-6Al-4V) stem, which is grit blasted allowing bone on-growth.

Inclusion of HA within the material attracts synovial fluid helping lubricate the articulation with cartilage. The hydrophilic capability can be observed when comparing the contact angle of a water droplet on its surface to one on standard UHMWPE (Fig. 1).[8]

BioPoly is 80 times stiffer than hyaline cartilage, but is much closer to the stiffness of cartilage than metal used in alternative surfacing implants (25,000 times stiffer). Material stability of BioPoly in vitro under oxidative stress, enzymatic degradation, and mechanical fatigue (10 million cycles) has shown it to be stable and without degradation.[9] Long-term studies have demonstrated a lower coefficient of friction and reduced wear compared to cobalt chrome alloys used in alternative focal resurfacing implants. However, it should be noted that the applied stress used for testing was lower than the maximum stress found in some joints.[10]

Compared to metal implants, BioPoly results in lower opposing cartilage contact pressures. Pressure mapping at 2.5 times bodyweight load has shown 52% lower contact pressure on the tibial surface and 50% greater contact load zone for BioPoly compared to a metal implant.[11] This has the effect of reducing compressive strains on the tibia by 66%. In vivo animal studies have demonstrated an absence of significant pathology/wear in the cartilage opposing the implant.[12] In our patients who have undergone subsequent arthroscopy, wear has not been observed on the opposing joint surface and a rim of fibrocartilage ongrowth around the implant has occurred (Fig. 2).

Indications and Patient Selection

The BioPoly knee implant is a focal resurfacing arthroplasty procedure for the treatment of chondral lesions <3 cm^2 on the weight-bearing area of the medial or lateral femoral condyles, the patella facets or trochlea. ICRS grade 2, 3, or 4 lesions are all suitable if symptomatic.

The disease should be monopolar in nature (affecting only one side of the joint), well contained by normal cartilage and with a maximum depth of <4 mm from the articular surface. Good quality of subchondral bone is important to support the implant and ideally a good volume of meniscal tissue within that compartment of the knee to share load. A stable knee with neutral alignment is recommended, so a concomitant ligament reconstruction or corrective osteotomy should be considered when planning cases preoperatively.

In terms of patient selection, the BioPoly implant is recommended for patients over the age of 21 with a body mass index of <35. In clinical practice, patients are often in a treatment gap, with an age range of approximately 35-55 years, the so-called prearthroplasty group. In the very young patients, biological chondral treatment options are a preferred. Absolute contraindications include system inflammatory joint disease and allergy to titanium alloy (Ti-6Al-4V), UHMWPE, or hyaluronan/HA.

Surgical Technique

Exposure to the lesion is performed according to the surgeon's preference. The implant is first sized by placing a trial over the defect, ensuring there is complete coverage. The defect must be contained with a shoulder of normal cartilage

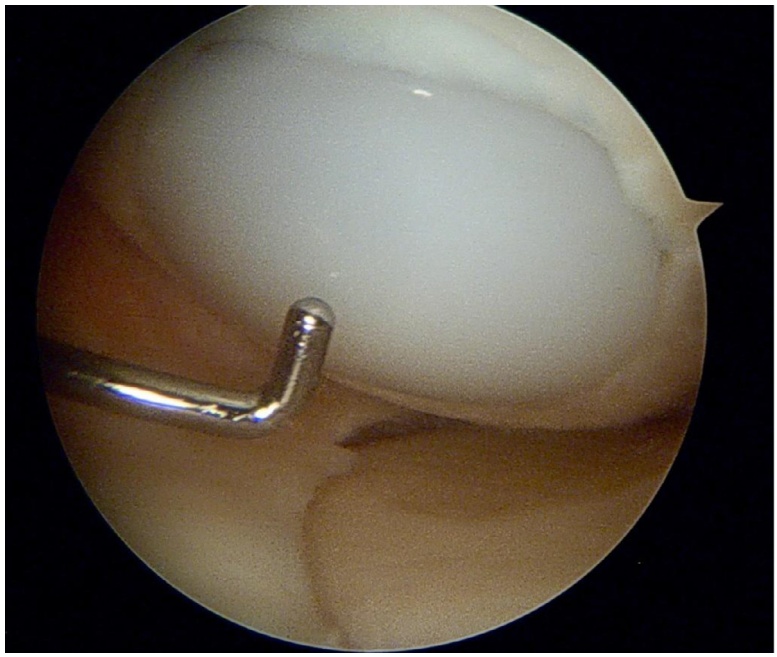

Figure 2 Arthroscopic image of 20-mm round BioPoly implant left knee at 12 months postoperatively. Note the healthy tibial cartilage in contact with the implant and the on growth of fibrocartilage.

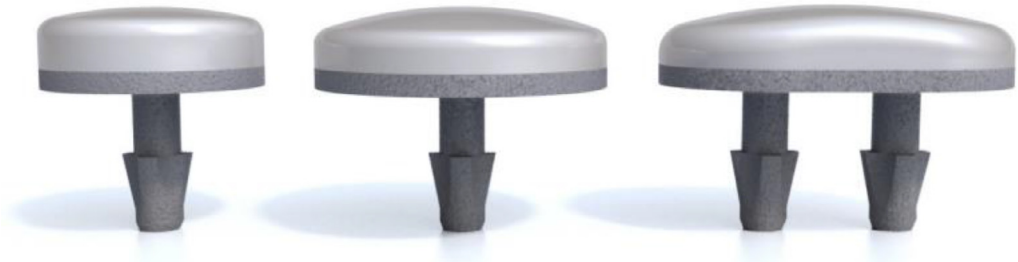

Figure 3 Photograph showing the different sizes of BioPoly RS partial resurfacing knee implant for the femur.

surrounding it. BioPoly RS Femur comes in 3 sizes (15 mm, 20 mm and 15 × 24 mm) (Fig. 3) and BioPoly RS Patella in 2 sizes (15 mm and 20 mm) each with size 0 or 1 thickness. BioPoly RS Trochlear has 2 sizes (15 and 20 mm) each with standard, shallow, and dysplastic trochlear shapes. The trochlear morphology can be assessed preoperatively using radiographs and intraoperatively using a gauge tool. For patella implants only, the thickness of the cartilage is measured using a probe to determine if a size 0 or 1 thickness implant is needed. A drill guide matching the component shape is then placed over the defect and a pilot wire placed. The system is cannulated, with a cutting cannula first used over the wire to cut through cartilage to subchondral bone followed by a reamer. A trial implant is then inserted and fit and depth checked. The top of the trial should ideally be recessed 0.5 mm below the articular cartilage. The trial is the same thickness as the implant; therefore, for the patella or trochlear implants, additional recession may be required to take into account the cement mantle. For trochlear implants, only a fin punch is aligned with the superior-inferior orientation of the trochlear groove (Whiteside's line) to create a slot for the implant that ensures correct rotation. Having confirmed fit, the definitive implant is then gently impacted into the prepared site (uncemented femur or trochlear) (Fig. 4) or cemented (patella or trochlear).

Rehabilitation

BioPoly knee resurfacing procedures can be performed easily as enhanced recovery day case surgery with no restriction on postoperative weight-bearing status, or range of motion and with no indication for use of an external knee brace. Venous thromboembolic prophylaxis is recommended as per the unit protocol. Patients commence outpatient physiotherapy as soon as possible and total recovery ranges between 3 and 9 months.

Clinical Cases

The applications of the BioPoly resurfacing implant can be seen in the following cases. In the first, a 47 years old fit and

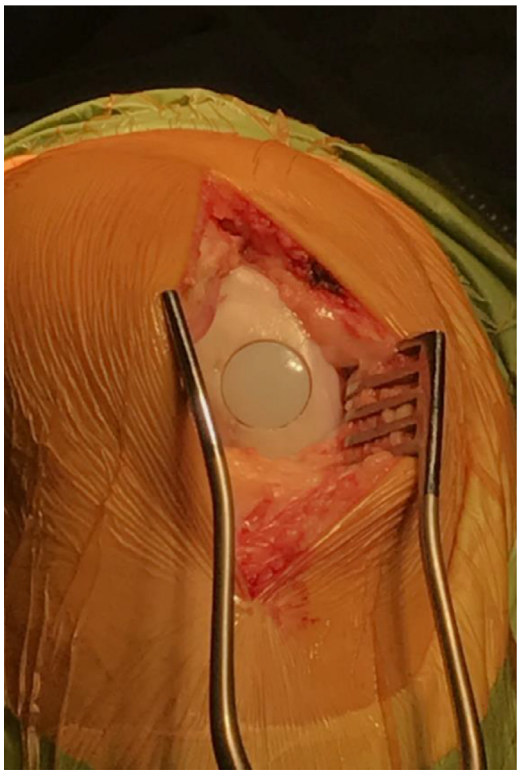

Figure 4 Intraoperative image showing a 20-mm round uncemented BioPoly implant on the medial femoral condyle right knee.

active patient with a symptomatic chondral lesion of the patella, causing pain which prevented her from enjoying hill walking. The patella chondral lesion and healthy trochlear cartilage can be seen on the MRI scan (Fig. 5) and intra-operatively (Fig. 6). A cemented BioPoly patella implant was used to completely cover the defect (Fig. 7).

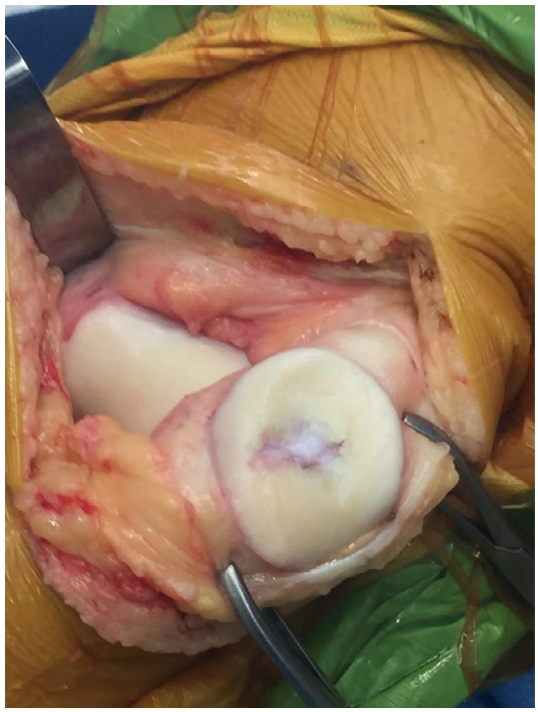

Figure 6 Intraoperative image showing the severe chondral lesion on lateral patella facet (left knee). Note the normal femoral trochlea.

The second, a 51 years old company director and triathlete with a chondral lesion on the medial femoral condyle. They

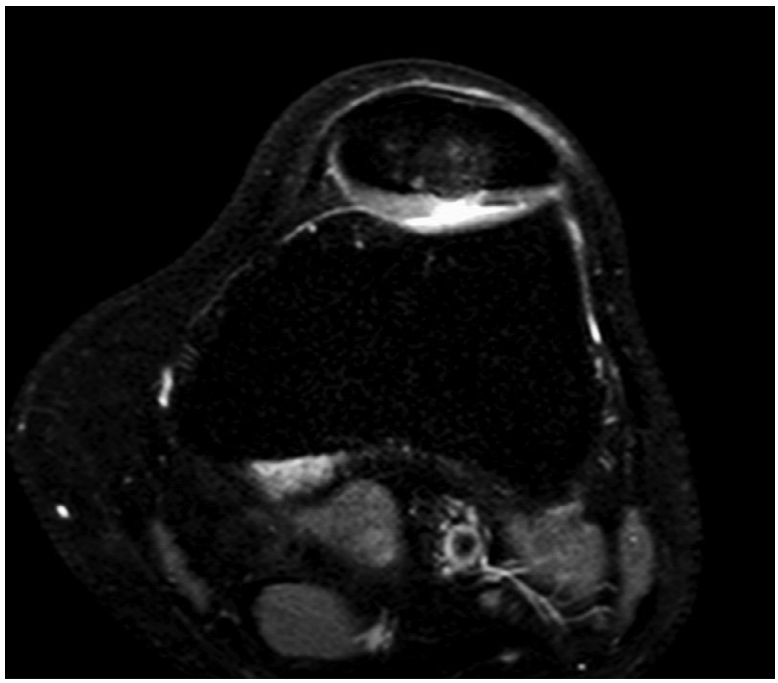

Figure 5 T2-weighted axial MRI scan left knee showing grade 4 chondral lesion of patella in a 47-year-old fit and active female teacher who enjoys hill walking.

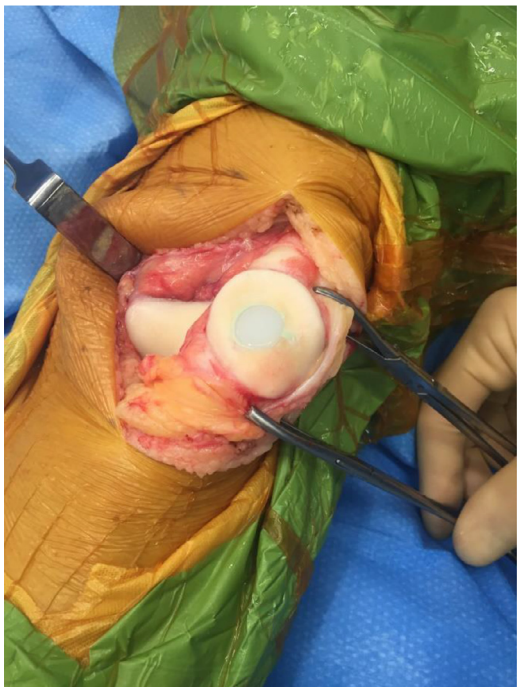

Figure 7 Intraoperative image showing a 15-mm round cemented BioPoly patella implant in situ.

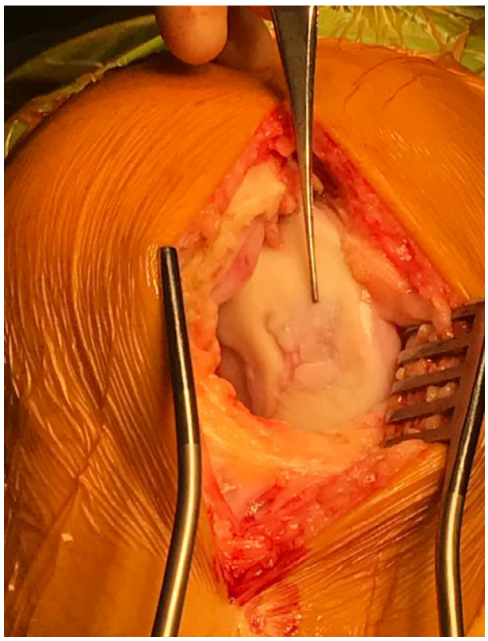

Figure 8 Intraoperative image of a chondral defect in the weight-bearing zone of the medial femoral condyle right knee.

had undergone a failed micro fracture procedure for this isolated lesion (Fig. 8), which currently in the UK makes them ineligible for cell-based therapies such as autologous chondrocyte implantation. This was treated using an uncemented BioPoly implant (Fig. 9).

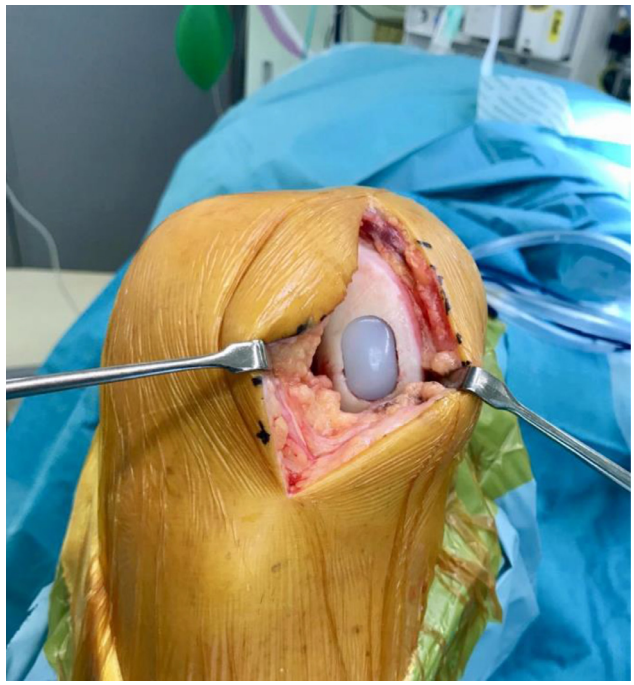

Figure 9 Intraoperative image showing a 24 × 15 mm oval uncemented BioPoly implant in situ.

Discussion

Partial knee resurfacing using non biological implants such as the BioPoly device have shown promising early results with low revision and complication rates, and with good patient-reported outcomes, but more long-term data and validation are required.[13] The indications and relative criteria for these innovative procedures remain narrow and accurate patient selection is paramount in order to achieve optimum results.

BioPoly appears to be a safe, bio inert option for younger active patients with symptomatic chondral lesions that are often in a so-called treatment gap within the "pre-arthroplasty" sphere. It allows for joint preservation with minimal bone loss and theoretically an easy revision to unicompartmental knee arthroplasty in the future, if required. Aseptic loosening is likely to be the predominant concern and mode of failure for implants of this nature and studies up to this point have had a limited follow up period in which this problem might occur. The 5-year result data are being prepared for publication imminently and is keenly awaited in addition to ongoing clinical trials to evaluate BioPoly survivorship in the medium to long term.

In terms of cost effectiveness, it may be a suitable option for some patients and surgeons when much more expensive biological or allograft treatment options are negated due to financial constraints. BioPoly may have a key role to play in the treatment of severe chondral lesions of the patella, an area where many biological surgical options have traditionally been associated with poor outcomes.

In the United Kingdom, BioPoly knee implant data are currently collected by the UK National Joint Registry but analysis is somewhat different to TKR or THR making clinical coding difficult. Also, the total number of cases performed annually is relatively small, making data collection and interpretation more challenging. The National Joint Registry aims to agree a minimum data set for all partial resurfacing implants (including metallic implants such as Arthosurface and Episealer) by the end of 2022. Collaborative work with the UK National Institute of Clinical excellence advisory committee is in progress and formal guidance is currently awaited.

BioPoly is not currently available or approved worldwide. At present BioPoly knee and patella implants have CE mark approval for use in Europe. In the United States, the great toe implants have 510(k) clearance and the knee implant has an investigational device exemption by the FDA allowing it to be used in clinical studies to collect data on its safety and effectiveness. The trochlear implant is currently only approved by the Malaysian Medical Device Agency.

Large number, long-term data on BioPoly are lacking. Published work is available with 2-year follow-up and soon to be available for 5 years. A multicenter UK registry study is ongoing for the patella implant.

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