Focal knee resurfacing

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Abstract

A significant number of patients suffer from focal articular damage that is neither appropriate for traditional arthroplasty, nor for biological repair. Since 2005, contoured focal resurfacing systems for the femoral condyle have been available that can cater for this specific subgroup of patients. Independent long-term data on these implants have previously been lacking, but are now becoming available. This review will look at: the basic biology of cartilage, the natural progression of focal cartilage disease in the knee, the surgical and non-surgical options available, the indications for focal resurfacing, surgical techniques, which implants are currently available, and the current clinical data with respect to these.

Keywords biopoly; chondral defect; episealer; focal; hemicap; knee; osteochondral defect; resurfacing

Hyaline cartilage

The knee articular surface consists of hyaline cartilage. This cartilage is integrated to underlying mineralized tissue. The role of hyaline cartilage is both that of shock absorption and facilitating low friction gliding of the joint surfaces. Its constituents are chondrocytes, extracellular matrix (consisting of collagens, proteoglycans, glycoproteins, and non-collagenous proteins) and interstitial water (which is thought to make up 60–80% of the weight).[1] Chondrocytes only contribute to 1% of the total volume, and are primarily responsible for the turnover, synthesis and remodelling of the extracellular matrix.[2] The collagen makeup in hyaline cartilage is typically 90% type II. Hyaline cartilage and the chondrocytes embedded within do not have a direct blood supply; it is the flow of water into and out of the solid permeable matrix and joint cavity that transports nutrients and metabolites to and from the chondrocytes, through the process of diffusion. Intermittent compressive forces across the joint aid this process.[3] The chondrocytes consequently have a low rate of proliferation and turnover.

Hyaline cartilage has four specific structurally distinguishable zones.[4] These include the superficial tangential zone, middle, deep and calcified zone. Beneath this is subchondral bone (Figure 1). This has led to different grading systems of cartilage damage; notably to the International Cartilage Regeneration & Joint Preservation Society scoring system (ICRS).[5] Grade I refers to 'nearly normal', whereby there may be soft indentation or superficial fissures. Grade II is 'abnormal' with loss of less than 50% of cartilage depth. Grade III is 'severely abnormal' with loss of more than 50% of cartilage depth, which can be down to the calcified layer, or to subchondral bone or with blisters. Grade IV describes lesions through to the calcified layer and subchondral surface.

Damage to cartilage in the knee

Focal cartilage defects refer to a specific area of loss of hyaline cartilage in the joint. Osteochondral defects refer to loss of cartilage and underlying subchondral bone, whereas a chondral defect refers to cartilage loss only. Symptoms of cartilage damage in the knee include pain, swelling and locking. Patients with focal lesions have been shown to experience a similar level of pain and dysfunction to those with severe osteoarthritis of the knee.[6]

Articular defects are common. Although the exact prevalence of these lesions in the general population is not clear,[7] in athletes with knee injuries it is thought to be 36%. In a prospective study looking at 1000 arthroscopies,[8] 19% of patients had some form of focal chondral or osteochondral lesion. Of these 58% were found on the medial femoral condyle, 11% on the patella, 9% on the lateral femoral condyle, 6% in the trochlea and 5% on the medial tibial plateau.

Hyaline cartilage is particularly susceptible to damage and has limited regeneration potential. The cartilage is avascular and therefore does not respond like normal tissues with inflammation to injury. The natural course of cartilage injury is not well understood, with some injuries leading to arthrosis. It is thought to be multifactorial, however, relating to the patient's age, weight, site of the lesion, depth of the lesion, joint laxity (for example concomitant ligamentous injury), and activity level.[1] If the lesion involves a weight-bearing area, any incongruity can lead to increased stress loading of adjacent cartilage and therefore increased wear.[9] It is thought that having one area of focal cartilage damage is also a risk factor for developing further areas of damage in the knee, irrespective of the depth.[10] Having lesions on the femoral condyles is a better prognostic sign than the

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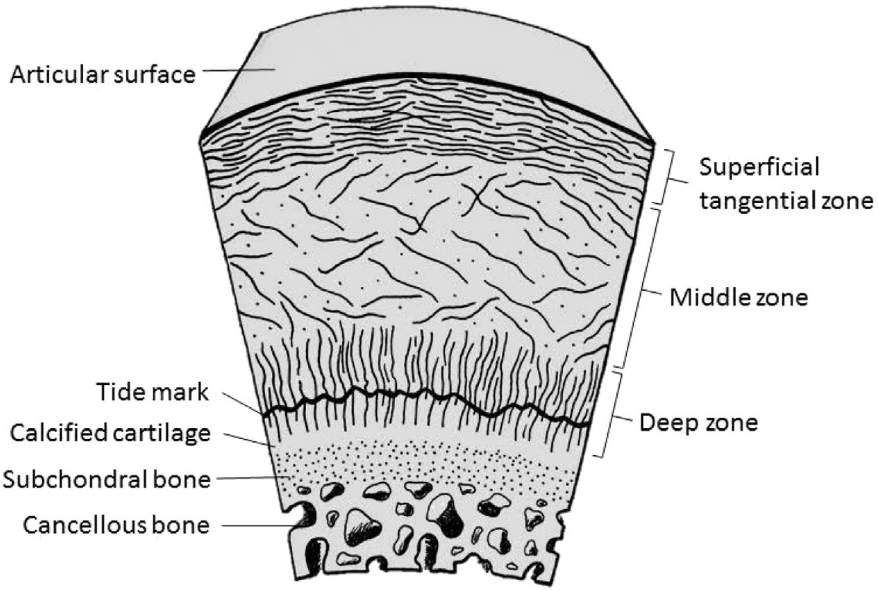

Figure 1 An illustration of the structure of cartilage. Illustration by Harry Hodgson.

tibia.[11] Increased weight, age, and activity levels all negatively affect prognosis.

The best treatment of full-thickness focal cartilage defects in the knee is still not established. Principles of treatment should focus on relieving pain, restoring joint function and preventing osteoarthritis.[12]

Imaging

Routine plain radiography should be performed, including: weight-bearing anteroposterior (AP), lateral, posteroanterior at 30° flexion and skyline views.[13] Lesions affecting the mineralized layer of bone will often be apparent on plain films.

Magnetic resonance imaging (MRI) allows direct evaluation of hyaline cartilage and is considered the best non-invasive assessment tool.[14] This reflects the complex biochemical and histological environment being examined. Information on chondral thickness, intrasubstance signal change, abnormalities at the surface, as well as the activity of underlying bone can all be assessed. Whilst T1 and T2 weighted images are routinely performed, T2 are the most sensitive in detecting lesions in hyaline cartilage.

Reported sensitivity of MRI in detecting chondral lesions depends on the protocol used and the size of the lesion. Use of high-quality 3-Tesla MRI scanners has significantly improved sensitivity. Using low quality 1.5-Tesla images, fibrillation may only be identified in 30%[14] of cases.

Medical treatment

Pain relief is the main goal of medical management for articular defects. Conservative measures include weight loss and activity modification. Medical options include simple analgesics or intra-articular injections (steroid or hyaluronic acid). With regards to analgesics, these should be approached in a stepwise fashion using the World Health Organization 'pain ladder'.[15] In the young patient with a significant articular defect, conservative management alone is not recommended due to the risk of developing further joint damage and, eventually, premature osteoarthritis.

Surgical treatment

Surgical management is patient-specific and depends on activity requirements. Site and size of cartilage defect is also crucial in guiding decision making. Surgical options are biological or non-biological. Biological options include marrow stimulation or osteoarticular autografting in small defects (less than 2.5 cm^2). Larger defects may require debridement, marrow stimulation, chondrocyte implantation or osteoarticular grafting (more than 2.5 cm^2).[12] Non-biological options include resurfacing and arthroplasty.

Marrow stimulation (one common technique of which is known as microfracture), is widely regarded by some as the first-line treatment for focal cartilage defects. This technique induces bleeding and inflammation, which stimulates propagation of mesenchymal stem cells by penetrating the subchondral bone surface. It has been shown fibrocartilage ingrowth can occur, which is more heavily composed of type I collagen. Although highly effective in the short-term, this makeup of non-hyaline cartilage biomechanically predisposes this method of repair to inevitable failure, with deterioration in clinical results commonly occurring after 18 months.[16]

Osteoarticular autografting (or osteochondral autograft transfer system (OATS)), otherwise known as mosaicplasty, is a technically challenging procedure whereby the surgeon must take a donor area of osteochondral 'plug' from a non-weight-bearing area in the trochlea and insert it into the defect with accuracy, whilst maintaining normal surface congruence. As the site of the graft must be the trochlea, this can limit the size of the graft (usually less than 400 mm^2).[17] At 10-year follow-up, outcomes from this procedure show no significant difference from microfracture[18] with regard to patient recorded or radiological outcomes.

Autologous chondrocyte implantation (ACI) is a two-stage cell-based repair technique. The initial procedure involves taking a sample of full-thickness cartilage from a non-weight-bearing portion of the knee and growing this in a culture medium in order to multiply the cartilage cells. The cells are then implanted back into the defect at a later date with a periosteal cover. The procedure has been associated with mixed failure rates; 17% being reported at 24 months,[19] and 57% failure at 10 years.[20] It is also associated with the complications of graft hypertrophy, calcification and delamination.[21]

Matrix induced autologous chondrocyte implantation (MACI), is similar to ACI; however, here the chondrocytes are cultured into a biodegradable scaffold and sealed in with a fibrin glue.[21] This is thought to prevent leakage of chondrocytes[22] and fibroblast ingrowth.[23] Histologically, it has been shown to be no more superior than ACI. Looking at the complications, graft hypertrophy alone has resulted in 6% of patients requiring re-operation at 1 year.[21] MACI has, however, been shown to be superior to microfracture in the short-term (at 2-year follow up).[24] The use of ACI and MACI involves multiple surgeries and lengthy and relatively difficult rehabilitation.

The use of these biologic treatments has been shown to be more favourable with younger patients (<30 years).[25] Biological methods are not suitable for elderly patients,[26] in whom arthroplasty may be preferable. Focal resurfacing may therefore be considered a bridge between the use of biologics in young patients and arthroplasty in elderly.

Focal resurfacing has been directly compared to biological methods and found to be significantly superior, with regards to patient outcomes and the need for further surgery, at a range of ages.[27]

Focal resurfacing of the femoral condyle

Focal resurfacing implants have been around for 15 years now, and longer-term data are becoming more available. The general premise of the use of these implants is to treat full-thickness articular defects of a relatively small area, to improve pain and function in the knee. The implants are designed to provide load sharing with a contoured new surface, while protecting the remaining healthy cartilage margins.[9] They are specifically used as a temporizing measure for patients who are symptomatic with a focal articular defect who need to get back to full activity quickly. Using a small resurfacing implant means there is less rehabilitation time and less bone resection, compared to partial or total knee arthroplasty (TKA). TKA has been shown to be effective in elderly patients[28]; however, TKA should only be undertaken judiciously in younger patients (<55) and only as a relative last resort, due to concerns regarding prosthetic longevity.[29] Younger patients have a higher functional demand and they often desire to return to a high level of activity quickly after surgery, which can increase implant wear. The failure rate in a TKA series at 10 years for patients under 50 has been shown to be 9–16%.[30,31]

Femoral resurfacing techniques can allow immediate weight-bearing while preserving anatomy. General contraindications from manufacturers and authors include: high body mass index, autoimmune arthritis, gout, uncorrected mal-alignment of the knee, ligamentous instability, presence of a 'kissing' lesion (anything ≥ Grade II[9]), the presence of opposing articulating components, non-localized defects, any infection in the body, and any allergy to materials present in the implants. Relative contraindications include the uncooperative patient, vascular or muscular insufficiency, inadequate bone stock or poor skin quality.

To the authors' knowledge, there are currently three brands of commercially available focal femoral resurfacing products available in the UK, which will be reviewed. These include the Hemicap, the Episealer, and the Biopoly implant. Some of these manufacturers also produce patellofemoral resurfacing implants, which falls under the remit of arthroplasty, and which will therefore not be reviewed in this article.

The surgical technique for the various implants is similar, with variations on the product specifics. The procedure can be commenced with a diagnostic arthroscopy, to confirm the diagnosis, diagnose any other damage within the knee, and to delineate the size and depth of the lesion. The authors recommend open arthrotomy for implantation. It is recommended an initial assessment be made to ensure that an appropriate trial will fully circumscribe the affected area before drilling. The drill guide must then be placed using a guidewire perpendicular to the defect (or in the case of the Episurf, multiple wires). It is essential at this stage to make sure the drill guide is seated appropriately, and covering the correct area of bone. The drill guide must be flush with the articular surface. The area is then drilled to the correct depth, as recommended by the manufacturer. The Biopoly and Episurf implants can be tapped down, whereas the Hemicap implant requires first the insertion of the fixation component and then the articular component, separately. Manufacturers give slightly varying information on the depth of insertion, but it is essential that the implant is recessed at least 0.5–1 mm below the articular surface in order to avoid early failure.

Hemicap

The Hemicap is a contoured articular prosthetic re-surfacing prosthesis (Arthrosurface Inc., Franklin, MA, USA)[32] (Figure 2). This consists of a rounded cobalt-chromium cap and a titanium screw post. This implant was introduced in 2003. It is recommended by the manufacturer for pain relief and improved function in patients with large unstable focal femoral defects affecting one compartment only. It may be used specifically used as a device of interim clinical strategy in those patients who, if left unattended, would likely progress with clinical symptoms and require total joint replacement. The Hemicap classic implant is

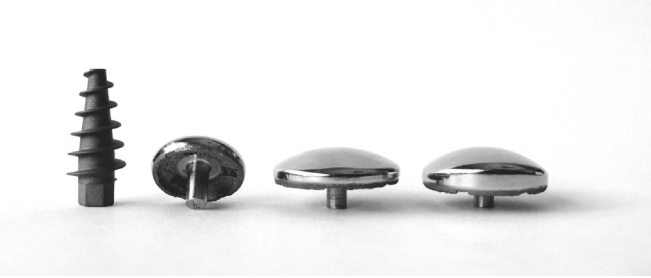

Figure 2 The Hemicap implant. Photograph provided courtesy of Arthrosurface.

available in 15 and 20 mm in diameters in different contours to match the patient's articular defect. It is essential that an accurate fit of the defect is made and that the implant is not elevated, in order to prevent meniscal or articular damage on the corresponding and opposite joint surfaces.

There are limited data on the long-term outcomes of the Hemicap implant. Becher[33] describes a series of 21 patients with 5-year follow-up. The patients had an average age of 54 at time of surgery. Most of his patients had failed previous surgery, in the form of microfracture or biological treatments. Patient recorded outcome measures (PROMs) improved significantly overall. Radiographic findings at follow-up showed no loosening and no change with regards to tibiofemoral osteoarthritis. Interestingly, Becher implanted 40 Hemicaps, but 17 were excluded as these did not match the manufacturers' guidelines or were aged over 65. The results of these elderly patients would have added value. Two patients in this study required further arthroscopic surgery for persistent pain, one of which required a high tibial osteotomy for malalignment. The scores for these patients were fair and poor. The latter patient was considered to have failed surgical treatment and was excluded from the study on the basis that their pre-operative malalignment contraindicated the use of this implant. They have reported data between 5 and 12 years, with what appears to be a substantial loss to follow-up.

Laursen[34] describes follow-up of 61 patients at 2–7 years, with a revision rate of 23%. The author reports, however, that follow-up was only completed for 67% of patients at 2 years. Functional scores were only obtained at 2 years and did show a significant improvement compared to pre-operative status.

Hobbs et al.[35] followed up 22 patients up to 4.7 years after surgery, with a revision rate of 13.6%. They report a significant improvement in sports and quality of life Knee injury and Osteoarthritis Outcome (KOOS) scores. The range of follow-up was 2–6 years, making this a relatively short-term follow-up.

Using multiple focal resurfacings in a single joint may increase the revision rate. The Australian Joint Registry 2017 annual report quotes a revision rate for the Hemicap of 38.7% at 9 years, from a total of 238 procedures.[36] This is significantly higher compared to other studies. They state out of 238 procedures, 177 used one cap, 56 used two and 5 used three caps No further detailed information other than anatomical location of the Hemicap implants is supplied by the registry. These data also includes patellofemoral resurfacing, and is therefore an heterogenous group.

Pascual-Garrido et al.[27] performed a study comparing outcomes of Hemicap implants with biological resurfacing (including debridement, microfracture, OATs, osteochondral allograft and ACI). A total of 32 patients were followed up 2.6 years in the biological group, and 32 patients for 2 years in the resurfacing group. Both groups were matched for age, anatomical location and defect grade and size. Again, the biological group represented a heterogeneous treatment arm, which will have confounded the results. Around half of the biological group had microfracture. The focal resurfacing group was overwhelmingly more successful, with 75% achieving 'success' comparted to only 53% in the biological group. Success was defined as an increase of 20% or more in the Western Ontario and McMaster Osteoarthritis (WOMAC) scores and not requiring any further procedures.

Episealer

The Episealer (Episurf Medical, Stockholm, Sweden),[37] like the Hemicap, uses a cobalt-chromium articulating surface (Figure 3). The undersurface and the peg (which is 4 x 15 mm in size) are sprayed with an osteophilic titanium and hydroxyapatite coating. The unique feature of this implant is that it is patient-specific and is custom-made for every case, including the associated cutting guides. This requires a preoperative MRI scan to be sent to the company, and the implant is calibrated on this for the correct anatomical fit. Unlike the other implants, there are a wider variety of sizes available, and the recommended use extends from femoral condyle to the trochlea. The theoretical advantage of this implant is a 'perfect fit' for the patient, minimizing the chance of failure due to anatomical malalignment or mismatch.

Due to the age of the implant (introduced in 2013), there are very limited clinical data available on this, and only very short-term follow-up.

Stalman et al.[38] reports a case series of 10 patients with 2-year clinical and radiostereometric analysis (RSA). All patients had isolated grade III or IV lesions and had failed earlier surgical intervention on the medial femoral condyle (in the form of drilling, abrasion or microfracture). One patient had previous anterior cruciate ligament reconstruction, and three partial menisectomy. The age range was from 30 to 65. Patients were apparently excluded from the study as recommended by the manufacturer. Results showed significantly improved functional outcome scores with regards to visual analogue score (VAS) pain, quality of life, activities of daily living, and sports and recreation. They reported no complications and no cases of radiographic loosening. One patient required arthroscopy at 10 months, and was found to have developed Grade II patellofemoral articular change. Improvements in EQ5D, KOOS pain, and KOOS symptoms were not significantly improved. RSA did show significant migration at 6 months postoperatively (maximal total point movement). However, as the author states, this is within a safe limit of 0.3 mm (which is the predictive distance for failure in total knee arthroplasty).[39]

Figure 3 Episealer implant. Photograph provided courtesy of Episurf Medical.

Biopoly

Biopoly (Schwartz Biomedical, Fort Wayne, USA)[40] is a biosynthetic implant with a bearing surface of ultra-high molecular weight polyethylene (UHMWPE) that is combined with hyaluronic acid (Figure 4). This bearing surface has been shown to have less wear, compared to UHMWPE, which is thought to be due to the hydrophilic nature of the hyaluronic acid.[41] The bearing surface rests on top of a titanium grit blasted stem. The sizes available are 15 mm diameter, 20 mm diameter and 15 mm x 24 mm. The implant can cover areas from 0.8 cm^2 up to 3.1 cm^2. The manufacturer recommends its use in Grade II, III or IV lesions. There is a significant difference in the stiffness quality of the articulating surface; being predominantly polyethelene, its surface is much softer than the metal surface of the Hemicap or the Episealer. The hypothesis is that there should be less corresponding surface wear as a result, and this has been shown in the early results. The technique and implant are fairly new, with the first human implantation in 2012.

There are only early data available in the literature with regards to this implant, and at the time of writing, only one case controlled series with clinical data was published (Nathwani et al.).[42] These cases were performed on medial or lateral femoral condyles only and performed using the manufacturer's recommended technique. 33 patients were included in the study in total, with a 2-year follow-up. Total follow-up time for this group was 5 years, and a similar study has now been approved and started for patellar facet defects. In this series at 2 years, only one patient required revision surgery at 2 years due to failure of osteointegration (revision rate 3%). This patient had previously undergone microfracture and ACI surgery in the same area, which may have resulted in altered subchondral bony metabolism. At all time points of follow-up, including 2 years, KOOS knee scoring and VAS pain scoring were significantly improved compared to pre-operatively. Patients also showed significant improvement with regards to quality of life, sports, activity of daily living, and pain, compared to historical outcomes for microfracture. The authors recommend the safe use of the implant regardless of age (range 22–65 years in the study). Current trials are ongoing for the patellar Biopoly implant, and further development is proceeding for other areas within the knee and other joints.

Figure 4 Biopoly implant. Photograph provided courtesy of Schwartz Biomedical.

Key considerations

As Ryd[43] states, there are three main issues surrounding the use of resurfacing implants in the knee. First, the implant must bond to the surrounding bone and be secure. All of the resurfacing implants for the knee use a titanium post, and titanium has been shown to have excellent bonding to bone.[44] However, if the bony bed is of poor quality, such as when there has been extensive previous surgery performed on the area, or if there is metabolic bone disease (such as osteoporosis), then this may affect osseointegration.

Second, the implant tribology must match that of the surrounding articular cartilage and therefore be accepted by the opposing articular cartilage. If the implant is not conforming to the opposing surface, failure will be inevitable.[45] Both cobalt-chromium and polyethylene have been shown to articulate well with cartilage, as in the case of total knee arthroplasty where the patella may or may not be resurfaced. However, there are ongoing concerns regarding the high stiffness of metal surfaces.

Third, the surrounding cartilage must accept the implant. The implant must not be positioned too deep or too proud. With a 1 mm proud implant, the mean contact pressures can increase by 217%. This will damage the cartilage on the opposing surface. When the implant is inserted flush, there is no increase in contact pressures according to biomechanical studies.[46] If the implant is too deep, the surrounding cartilage will be damaged due to the 'pot hole' effect.[43]

A fourth consideration is that of the overall 'health' of the knee. A knee that has had multiple surgeries and or injuries previously may well have low grade inflammation. This can be damaging to articular cartilage and speed disease progression in other areas of the knee. Di Chen[47] describes that when the inflammatory process starts, the synovium, subchondral bone and articular cartilage are all involved in a spiral of inflammation. Inflammatory factors such as IL-1β, TNF-α and chemokines contribute to the inflammation. This triggers a response throughout the knee. This can explain how osteoarthritis in one area of the knee can produce disease progression in a relatively unaffected area of the joint. If the knee has had multiple injuries or surgeries previously, then one should be cautious in performing isolated resurfacing.

Further studies

Key areas identified that require further analysis and study include:

- Longer term follow-up of current studies
- Comparing results of patients with primary resurfacing surgery with patients who have had previous failed biologic surgery
- Results for patients resurfaced with multiple injuries in the knee compared to isolated injuries
- The results of the elderly population compared to younger controls. Perhaps age alone should not be a confounder in the use of these implants, as shown in the Biopoly study
- Study of outcomes of larger resurfacing *versus* smaller resurfacings

Key points

- Resurfacing is probably best reserved for middle-aged patients
- Ensure that the implant is anatomical and recessed by 0.5–1 mm
- Carefully follow the manufacturers guidelines with regard to exclusion and inclusion criteria
- Be careful when using these implants in the multiply previously injured/operated knee
- Always have a second option available should the focal resurfacing be unsuccessful

Conclusions

The focal femoral resurfacing implant is a safe and effective bone and cartilage preserving procedure, which does not compromise potential future arthroplasty surgery. Long-term outcome data are starting to show excellent clinical outcomes. Mid-term revision rates are variable, and longer-term outcome data is required. We encourage other surgeons to consider this as a possible alternative to biological methods in middle-aged patients. ◆

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