Bipolar fresh osteochondral allograft for the treatment of end-stage osteoarthritis: comprehensive multi-joint evidence supported by long-term experience

Sandro Giannini¹, Antonio Mazzotti^{2,3}, Alberto Arceri^{2,3}

¹ Professor Emeritus, University of Bologna, Bologna, Italy: ²1st Orthopaedics and Traumatologic Clinic, IRCCS Istituto Ortopedico Rizzoli, Bologna, Italy: ³ Department of Biomedical and Neuromotor Sciences, University of Bologna, Bologna, Italy

ABSTRACT

Bipolar fresh osteochondral allograft (BFOA) has emerged as a biologically based alternative for joint resurfacing in the treatment of end-stage osteoarthritis, particularly in young and active patients for whom traditional interventions such as arthrodesis or prosthetic replacement may be suboptimal. This review synthesizes recent clinical evidence on the application of BFOA across multiple anatomical sites, namely the shoulder, knee, ankle, and first metatarsophalangeal joint (1MTPJ). The technique involves transplanting viable articular cartilage with an intact subchondral bone layer to restore joint function and alleviate pain, with outcomes largely influenced by the biomechanical environment and local soft tissue conditions. In the shoulder, limited studies have demonstrated promising improvements in clinical scores. The knee, by contrast, has shown a markedly high failure rate; complications such as graft malalignment, poor fixation, and an adverse immunologic response-possibly due to the larger graft size and extensive soft tissue involvement-have contributed to suboptimal outcomes. In the ankle, many patients have reported pain relief and functional improvement. Similar encouraging results have been observed in the treatment of hallux rigidus at the 1MTPJ, where lower mechanical demands favor graft integration.

While BFOA offers a promising joint-preserving strategy for end-stage osteoarthritis, its efficacy varies by joint, highlighting the need for technical precision and careful patient selection to optimize BFOA outcomes. Further research is warranted, aimed at modulating host immune responses to enhance graft durability.

KEYWORDS

Bipolar fresh allograft, osteochondral allograft, ankle, hallux, knee, shoulder.

Introduction

Severe post-traumatic arthritis presents a significant reconstructive challenge, particularly in young and active patients. Traditional surgical approaches, including arthroplasty and arthrodesis, have limitations such as prosthetic loosening, high revision rates over time, and possible nonacceptance of these treatments by patients [1-3]. Bipolar fresh osteochondral allograft (BFOA) is a biological approach to joint resurfacing that has been explored in several anatomical regions as an alternative to more traditional surgical procedures [4,5]. The rationale behind this technique lies in its ability to transplant viable articular cartilage along with a preserved subchondral bone layer, thereby providing a biologically active resurfacing option intended to restore joint function and alleviate pain. Although the underlying principles of BFOA remain consistent across different joints, its clinical outcomes appear to be highly dependent on both the biomechanical environment of the target joint and the local soft tissue conditions [4,6].

This review provides valuable recent insights into the application of BFOA in the treatment of end-stage osteoarthritis in different anatomical sites.

To compile it, we selected the most recent follow-up re-

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Contact

Antonio Mazzotti; antonio.mazzotti@ior.it 1st Orthopaedics and Traumatologic Clinic, IRCCS Istituto Ortopedico Rizzoli, Bologna, Italy

ports from authors who have published multiple studies over the years on the same patient cohorts. Earlier publications often provide preliminary results, whereas subsequent reports offer a more comprehensive assessment of long-term graft survival, failure rates, and patient-reported outcomes. Aiming to present the most accurate and up-to-date evidence on the efficacy and durability of BFOA transplantation in the treatment of endstage osteoarthritis, we included only the latest follow-up data from each author.

Population

The primary indication for the procedure, as reported in the literature, was end-stage arthritis in young patients, although

selected cases previously treated with arthrodesis underwent conversion to BFOA ^[6,7]. The main contraindications were rheumatologic disease, osteoporosis, osteonecrosis, untreated limb malalignment, and active joint infection; and at the shoulder, rotator cuff pathology ^[4], although some authors included rheumatoid arthritis among the inclusion criteria ^[8]. The complete demographic data of the patients are reported in Table I.

The anatomical sites where BFOA has been used are the shoulder, knee, ankle, and first metatarsophalangeal joint (1MTPJ) (Table I).

Surgical technique

Donor joints were obtained by complete *en bloc* excision of the joint. Allografts were preserved using two distinct methods: some authors placed grafts in sterile plastic bags filled with Ringer's lactate solution supplemented with antibiotics [10,11], whereas others maintained grafts in a sterile solution containing L-glutamine, NaHCO₃, and antibiotics [6]; in both cases the solution was kept at 4°C. Allografts were transplanted within five [10], seven [11], or in some studies 16 days of harvesting [6,7,13]. When it was time for surgery, the graft was meticulously prepared on a separate table by removing all soft tissues while ensuring that the articular cartilage remained intact. Special care was taken to preserve approximately 10 to 12 millimeters of subchondral bone, which is crucial for maintaining the integrity of the graft. The prepared grafts were then temporarily stored in a saline solution until implantation.

The surgical technique used to resurface both the glenoid and the humeral head using fresh osteochondral allografts involved a standard deltoid-pectoral approach. The recipient joint was prepared, and the allograft components were inserted and fixed with small fragment and twist-off screws [9] (Figure 1).

At the knee, the surgical procedure involved resurfacing both the tibiofemoral and patellofemoral compartments with the allograft components, which were fixed using appropriate internal fixation devices [7] (Figure 1).

The ankle surgery entailed meticulous preparation of the recipient site, via either a lateral or an anterior approach, depending on anatomical and surgical considerations.

The degenerated joint surfaces were resected, and the allograft components were positioned and secured using pins, screws, or titanium fixation devices [6] (Figure 1).

A similar procedure was performed for 1MTPJ preparation. The degenerated articular surfaces were resected and the allograft was then carefully inserted and secured with twist-off screws under fluoroscopic guidance [13] (Figure 1).

Intraoperative fluoroscopy was employed to confirm proper alignment and stability. Following implantation, the joint capsule was meticulously sutured, and a postoperative immobilization protocol was initiated to facilitate graft integration and healing [6,7,13].

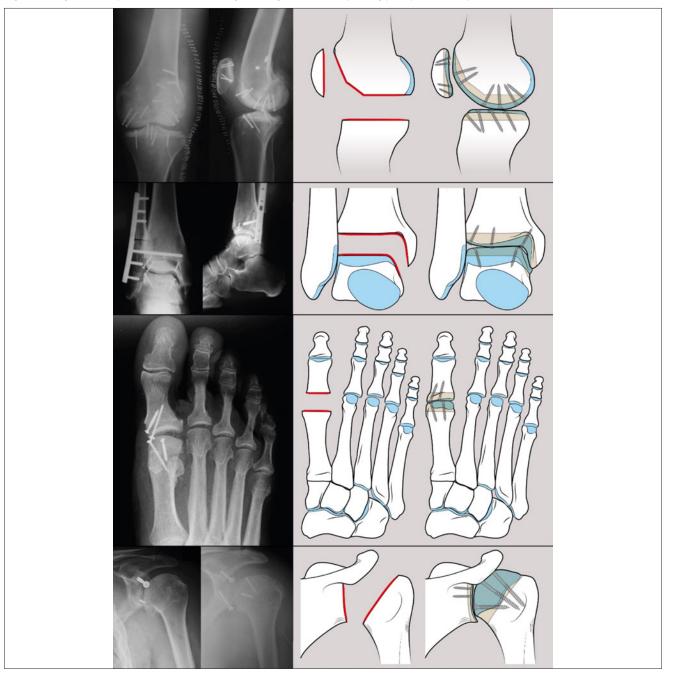
BFOA for the treatment end-stage shoulder osteoarthritis

Only one study [9], conducted by our group, reported application of BFOA in the shoulder. The study involved a small cohort of three patients (Table I) with severe post-traumatic osteoarthritis. The clinical outcomes, as measured by the Constant Score, showed a significant improvement from a preoperative average of 38.3 to 78.7 at 12 months, although there was a marked decline to 59.3 at the last follow-up, performed at 34 months (Table II). Radiographic assessments confirmed that the grafts had integrated well in the early postoperative period, with CT and MRI scans demonstrating a maintained cartilage layer and evidence of osseointegration. However, despite these positive early findings, gradual development of arthritic changes and partial reabsorption of the implanted surfaces occurred over time. One of the patients experienced joint laxity, which negatively impacted the final clinical outcome. However, no case failed, resulting in a reported survival rate of 100% at the last follow-up. This outcome, considered particularly favorable, may be attributed to both the lower mechanical demands of the shoulder and the careful patient selection, which excluded cases with rotator cuff pathology. These findings suggest that BFOA may offer a viable alternative for patients with severe post-traumatic shoulder arthritis, particularly those for whom traditional arthroplasty may not be ideal. However, concerns remain regarding the long-term durability of the graft and the potential for degenerative changes that could compromise joint function.

Table I Demographic data.

Table 1 Definographic data.						
STUDY	JOINT	PATIENTS	AGE (Mean ± SD)	SEX	FOLLOW-UP (Months)	
Giannini, <i>et al.</i> – 2013 ^[9]	Shoulder	3	44.0 ± 3.6	2M, 1F	34.6 ± 4.0	
Giannini, <i>et al.</i> – 2015 [7]	Knee	7	38.3 ± 8.9	5M, 2F	48	
Kim, et al. – 2002 [10]	Ankle	7	45 ± 6.6	2M, 5F	148	
Meehan, et al. – 2005 [11]	Ankle	9	43 ± 9.4	3M, 6F	33	
Jeng, <i>et al.</i> -2008 [8]	Ankle	29	41 ± 7.8	15M, 14F	24	
Giannini, <i>et al.</i> – 2017 ^[6]	Ankle	57	35.5 ± 7.9	41M, 16F	121± 18	
French, et al. – 2019 [12]	Ankle	82	44.3 ± 10.6	46M, 36F	110	
Giannini, <i>et al.</i> – 2013 [13]	1MTPJ	4 (2 bilateral)	51.0 ± 20.2	4F	57.0 ± 3.5	

Figure 1 Surgical technique for each anatomical region, alongside the corresponding postoperative X-rays.



BFOA for the treatment end-stage knee osteoarthritis

Although BFOA has been employed in a variety of pathological conditions affecting the knee [14-16], its use in the treatment of end-stage knee osteoarthritis has been examined in only one study [7], by our group. We investigated the procedure performed in seven knees in a relatively young cohort of patients (Table I) with post-traumatic osteoarthritis. Despite technically successful surgery without intraoperative complications, these patients' clinical course was marred by the development of joint laxity and aseptic effusion. These adverse events were accompanied by progressive chondrolysis, which ultimately led to a catastrophic failure of the allograft in six out of the seven treated knees. The failures occurred at an average follow-up of ap-

proximately 19.5 months, necessitating conversion to revision total knee arthroplasty. Only one patient, who had previously undergone a knee arthrodesis and thus underwent conversion to BFOA, achieved a satisfactory outcome (Table II). These results correspond to an approximate graft survival rate of 14.3% in the knee, suggesting that the extensive size of the graft and the significant amount of soft tissue involved in knee resurfacing might predispose the joint to an immunologic reaction, in turn compromising the graft integrity and stability. This immunologic response, possibly compounded by biomechanical factors unique to the knee joint, appears to play a central role in the high failure rate observed in this series, highlighting the limitations of BFOA in a weight-bearing joint that is subject to complex mechanical forces and extensive soft tissue dynamics.

BFOA for the treatment of end-stage ankle arthritis

The most extensive literature on this topic focused on the ankle. In a long-term (12-year) follow-up study [10] of seven patients who underwent BFOA transplantation for post-traumatic ankle arthritis, the ankle score improved from 25 preoperatively to 43 at final follow-up, while the SF-12 Physical Component score increased from 30 to 38, and the Mental Component score from 46 to 53. However, three of the patients (42%) experienced graft failure, requiring either revision surgery or conversion to arthrodesis. Despite this, four patients (57%) reported good or excellent outcomes, and five (71%) stated they would undergo the procedure again (Table II).

In a study [11] of nine patients who underwent BFOA transplantation for post-traumatic and degenerative ankle arthritis, outcomes were assessed over a mean follow-up of 33 months. The American Orthopaedic Foot and Ankle Society (AOFAS) score showed a significant improvement, rising from 55 preoperatively to 73 postoperatively (p = 0.01). However, five patients (45%) experienced graft failure, requiring revision allografting (3 cases), conversion to total ankle arthroplasty (1 case), or no further surgical intervention despite graft collapse (1 case) (Table II).

In a retrospective study [8] analyzing 29 patients who underwent BFOA transplantation for end-stage ankle arthritis, with a mean follow-up period of 24 months, a high failure rate was reported, with 14 of the patients (48%) requiring revision surgeries, including repeat allografting, total ankle arthroplasty, or ankle fusion. An additional six cases (21%) showed radiographic failure, leaving only 9 patients (31%) with successful long-term graft survival (Table II).

A large cohort of 86 patients [12] who underwent BFOA transplantation for end-stage ankle arthritis, with a mean follow-up period of 9.2 years, showed a significant improvement in functional outcomes, according to the Olerud-Molander Ankle Score which improved from a mean of 27.7 preoperatively to 52.2 at last follow-up (p < 0.001). However, 41% of the patients experienced graft failure, necessitating revision surgery, conversion to arthrodesis (10 cases), total ankle arthroplasty (7 cases), or even amputation (2 cases). The overall allograft survival rate was 74.8% at five years, dropping to 56% at 10 years (Table II).

Long-term follow-up of BFOA transplantation demonstrated that, despite a significant failure rate, most surviving grafts provided pain relief and functional improvement. A progressive reduction in ankle joint movement was noted, although this did not always correlate with patient-reported outcomes.

Our team published a study ^[6] evaluating 48 patients who underwent BFOA transplantation for post-traumatic end-stage ankle arthritis. The clinical and radiographic results were assessed over a mean follow-up period of 10 years. We found a significant improvement in the AOFAS score, which rose from a preoperative mean of 31 ± 11 to 65 ± 25 at final follow-up (p < 0.0005). However, 14 patients (29.2%) experienced graft failure, requiring conversion to either ankle fusion or arthroplasty (Table II). Despite the satisfactory clinical outcomes in most patients, a progressive reduction in ankle joint range of motion (ROM) was observed over time, with some cases eventually resulting in spontaneous arthrodesis.

Notably, as observed in all studies on the ankle, radiographic evidence of joint degeneration did not necessarily correlate with worse clinical outcomes. The findings therefore underscore the absence of a direct relationship between radiographic joint osteoarthritis and clinical performance, suggesting that pain relief and functional satisfaction may be obtained independently of structural deterioration [6,8,10-12].

Finally, several investigations have highlighted the critical role of technical precision and patient selection, with failures frequently attributed to graft malalignment, inadequate fixation, or subluxation [10], as well as to higher BMI in patients with severe preoperative angular deformity [8].

BFOA for the treatment of end-stage arthritis of the first metatarsophalangeal joint

We have also used the BFOA technique to treat small joint disease, namely end-stage osteoarthritis of the 1MTPJ [13]. The condition of hallux rigidus is characterized by pain and a marked reduction in joint mobility, particularly in dorsiflexion, due to degenerative changes that are often advanced by the time surgical intervention is considered necessary. Over a mean follow-up period of approximately six years, the clinical outcomes were encouraging, with the AOFAS score rising markedly from an average preoperative value of around 28.7 to

Table II Main outcomes and survival rates.

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STUDY	SCORES	PRE-OP.	FINAL-FU	SURVIVAL RATE			
Giannini, <i>et al.</i> – 2013 ^[9]	Constant Score (shoulder)	38.3 ± 2.9	59.3 ± 22.0	100%			
Giannini, <i>et al.</i> – 2015 ^[7]	IKDC score (knee)	33.7 ± 4.0	48	14.3%			
Kim, et al. – 2002 [10]	ankle score	25	43	58%			
Meehan, <i>et al.</i> – 2005 [11]	AOFAS score (ankle)	55	73	55%			
Jeng, <i>et al.</i> – 2008 [8]	-	-	-	31%			
Giannini, <i>et al.</i> – 2017 ^[6]	AOFAS score (ankle)	29.5 ± 10.9	72.5 ± 13.3	70.8%			
French, et al. – 2019 [12]	Olerud-Molander ankle Score	27.7 ± 15.5	52.2 ± 25.4	56%			
Giannini, <i>et al.</i> – 2013 [13]	AOFAS score (1st MTPJ)	28.7 ± 4.1	87.3 ± 2.6	66.7%			

approximately 87.2 postoperatively, and with a final ROM that, although limited to an average of 37.6 degrees, was deemed functionally adequate by the patients. Despite these positive results, the study also reported significant complications (dehiscence and infection) in one patient, attributed in part to previous surgical intervention for hallux valgus correction, which had already compromised the vascular supply to the first ray. Our experience with BFOA in the treatment of hallux rigidus thus underscores both the potential benefits of this joint-sparing technique and the critical importance of meticulous patient selection and technical precision in ensuring long-term graft survival and function.

Discussion

The divergent outcomes observed in the four anatomical sites underscore the importance of the local joint environment in determining the success of BFOA. In the case of the hallux, the relatively low mechanical demands and limited soft tissue envelope surrounding the 1MTPJ appear to favor more stable integration of the allograft, resulting in substantial improvements in function and pain relief over an extended follow-up period [13]. Conversely, the knee joint, with its complex biomechanical demands and extensive involvement of soft tissue structures, poses significant challenges that may predispose the graft to immunologic rejection and mechanical failure [7]. The shoulder is not burdened by weight-bearing stresses to the same extent as the knee, although it is subject to considerable shear and compressive forces, and the presence of an intact rotator cuff is critical to maintaining joint stability postoperatively [9].

Literature on the ankle suggests that weight-bearing could be a critical factor contributing to graft failure. For instance, Bugbee's group [10-12] reported a higher incidence of graft failures, which may be attributed to several factors, including early weight-bearing. In contrast, our series involving lower limb—specifically knee and ankle—procedures demonstrated a lower failure rate, a finding that may be associated with our protocol mandating a six-month period of complete non-weight-bearing [6].

The immunologic challenges associated with BFOA are also of particular interest. In the knee study ^[7], the authors highlighted the possibility that the large size of the graft and the extensive soft tissue components introduced into the joint might trigger an immunologic response.

This response, characterized by joint laxity, aseptic effusion, and progressive chondrolysis, ultimately led to graft failure in the majority of cases. The notion that biomechanical factors and immunologic reactions are intertwined in the context of osteochondral allografts is not entirely new; previous studies have suggested that the viability of chondrocytes and the integrity of the transplanted cartilage are influenced not only by surgical technique and mechanical stability, but also by the host's immune response [5,17].

The observation that the knee, with its larger graft size and

greater soft tissue involvement, exhibits a higher failure rate compared with the ankle and hallux suggests that there may be a threshold beyond which the immunologic burden becomes too great for the graft to overcome. In the shoulder study [9], the use of a light postoperative immunosuppressive therapy regimen was an attempt to counteract this potential rejection process, yet the results indicate that this intervention may be insufficient to fully prevent the degenerative changes that occur over time. This underscores the need for further research into strategies that could modulate the host immune response more effectively, perhaps through targeted immunotherapy or by optimizing the processing and storage of the allograft tissue to reduce its immunogenicity.

In all cases, the success of BFOA is intricately linked to a precise surgical technique and post-operative protocol, careful patient selection, and the ability to manage the local immunologic environment.

The clinical implications of these findings are significant. For patients suffering from end-stage joint arthritis, particularly those who are young and active with high functional demands, the prospect of a joint-sparing procedure such as BFOA is highly appealing. Traditional treatment options like arthrodesis, while effective in alleviating pain, come at the cost of joint mobility, and prosthetic replacement carries its own set of complications, especially in younger populations where implant longevity is a concern [18]. BFOA can provide substantial improvements in both pain relief and functional outcomes, offering a viable alternative to joint fusion or arthroplasty.

Conclusion

Our comparative analysis of BFOA across different anatomical sites reveals a nuanced picture of both the potential benefits and the inherent limitations of this biological resurfacing approach. These findings emphasize the need for a tailored approach to the use of BFOA, one that takes into account the specific demands and characteristics of each joint.

Despite literature reports of recurrence of radiographically evident osteoarthritis in all implanted allografts, the severity of these osteoarthritic changes did not appear to correlate with inferior clinical outcomes. And while fresh total osteochondral allograft implantation is technically challenging, this biological joint replacement strategy has achieved satisfactory long-term results in the shoulder, ankle, and hallux in a substantial number of young patients with high functional demands. Given that BFOA failure may be, at least in part, dependent on the host's immunologic response, further research is essential. Specifically, more detailed investigations into the immunologic behavior of the transplanted cartilage and the underlying mechanisms responsible for the gradual onset of osteoarthritis are needed. Such studies will not only help improve the outcomes of these procedures, but also potentially extend the application of this technique to other anatomical regions.

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