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RESEARCH ARTICLE

Optimizing Patient Outcomes Following Osteochondral Allograft Transplantation: The Impact of 25 Years of Translational and Clinical Research

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ABSTRACT

This manuscript consolidates 25 years of interdisciplinary research and clinical advancement in optimizing patient outcomes following osteochondral allograft (OCA) transplantation. In this manuscript, we detail the results of over 1500 OCA procedures and 115 research publications, integrating hypothesis-driven basic science and translational research with clinical outcomes data. The study highlights groundbreaking advancements, including: Innovations in fresh OCA preservation techniques that extend graft viability; Minimization of immunogenic, thermal, and impaction effects to enhance graft integration and durability; Cutting-edge methods for donor-recipient topographic matching, supported by 3D modeling; Evolution of the surgical technique, including the development of orthobiologic approaches to optimize outcomes; Evaluating long-term clinical outcomes and the effect of concomitant procedures; Decision-support algorithms that improve patient selection and surgical planning using machine learning tools. This manuscript illustrates the evolution of OCA transplantation into a reproducible, globally adopted technique for cartilage restoration. By merging basic science, translational insights, and clinical expertise, we redefine and improve the standards of graft handling, surgical technique, and clinical outcomes. The resulting data-driven guidelines and decision-support tools set a foundation for advancing the field, improving accessibility and patient selection, and enhancing patient outcomes worldwide.

1 | Introduction

Focal chondral or osteochondral defects of the knee are estimated to be present in 4.2% of the general population, 6.2% of patients under 40 years old, and up to 36% in athletes [1]. To address the symptoms associated with focal osteochondral defects of the knee, over 200,000 surgeries are performed annually [1, 2]. Surgical interventions range on the spectrum of palliative-reparative-restorative-reconstructive and include chondroplasty, marrow stimulation techniques (microfracture or microfracture+), matrix-induced autologous chondrocyte implantation (ACI/MACI), and osteochondral grafting (autografts and allografts) [3].

Osteochondral allograft (OCA) transplantation restores both the cartilaginous and osseous components. OCA transplantation is also

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unique in its ability to closely restore both the structural integrity and biological attributes without associated donor-site morbidity [4]. The implementation of OCA transplantation has increased annually over the past two decades [5, 6]. Specifically, OCA transplantation demonstrated increased use from 2005 to 2011 at a rate of 245% and increased an additional 160% from 2010 to 2016 [5, 6]. OCA transplantation is now the most frequently performed cartilage restoration technique (5.5 ± 2.5 per 100,000 procedures) [5].

In this manuscript, we describe the comprehensive body of work accumulated over 25 years at a high-volume academic cartilage restoration center, which has performed over 1500 OCA procedures to date. This body of work addresses clinically relevant barriers to the long-term success of OCA via hypothesis-driven research using a team-science collaborative approach. The contents of this manuscript will first summarize the comprehensive basic science and translational work and demonstrate how these findings are integrated to optimize the surgical technique and improve clinical outcomes. We will also present long-term clinical outcomes and decision-support algorithms aimed at improving patient indications and optimizing patient care.

2 | Basic Science and Translational Research

2.1 | Optimizing Fresh OCA Preservation

A major constraint related to the transplantation of fresh OCAs stems from the need for tissue processing agencies to provide allografts with a high rate of viable chondrocytes [7]. Preservation of cell viability is considered paramount to graft viability and historically, the time from donor asystole to graft implantation was limited to 7 days, creating severe logistical limitations [7]. To challenge this assumption, we obtained canine femoral condyles and stored them at 4°C for 14, 21, or 28 days and assessed specimens for cell viability, ^{35}S uptake, proteoglycan content, and histologic parameters. We found reduced Safranin-O near the cartilage surface at 14 days, which recovered at 21 and 28 days of cold preservation. Cell viability was found to be > 95%, 75%–98%, and 65%–90% at 14, 21, and 28 days, respectively (Figure 1A). Cell functionality, as assessed by the level of $^{35}SO_4$ incorporation reduced over time (Figure 1B). However, there were no statistically significant differences between groups, suggesting cold-preserved OCA material may be implanted within 28 days of harvest [7]. Consequently, most tissue banks today adopt 28 days as the cutoff for fresh OCA prolonged preservation and implantation.

Further, to reverse the suppressed metabolic effect of cold preservation, we evaluated the impact of graft rewarming protocols and nitric oxide (NO) production in bovine and canine models [8]. We found gradual rewarming of the graft (4° → 25° → 37°) and decreasing NO production by nitric oxide synthase (NOS) inhibition at the time of graft implantation can minimize the loss of chondrocytes' metabolic function [8]. Consequently, gradual rewarming of fresh OCA grafts has now become the operative standard (Figure 2A,B).

2.2 | Minimizing Detrimental Effects of Thermal Energy

OCA transplantation is often preceded by an index staging arthroscopy to evaluate the lesion and for concomitant pathologies. During the staging procedure, a chondroplasty is usually performed, as this leads to improved short-term clinical outcomes in many cases and may help better delineate the true margins of the defect [9]. In the past, radiofrequency devices were frequently utilized to perform chondroplasty. In 2001, we assessed the effect of bipolar radiofrequency energy (bRFE) on human articular cartilage [10]. Twelve cartilage specimens were treated with the ArthroCare 2000 bRFE system (ArthroCare, Sunnyvale, CA) coupled with one of two types of probes and at three energy delivery settings (S2, S4, S6). Confocal laser microscopy demonstrated that the depth and width of chondrocyte death were directly correlated to increasing bRFE settings. A complementary study was performed on 36 osteochondral specimens and demonstrated that bRFE created significantly greater chondrocyte death when compared to monopolar RFE [11]. Furthermore, our additional laboratory investigation demonstrated that thermal chondroplasty using a 37°C lavage solution resulted in less depth of chondrocyte death and produced smoother surfaces than when a 22°C solution was used, demonstrating the importance of controlling lavage solution temperature [12]. These findings led

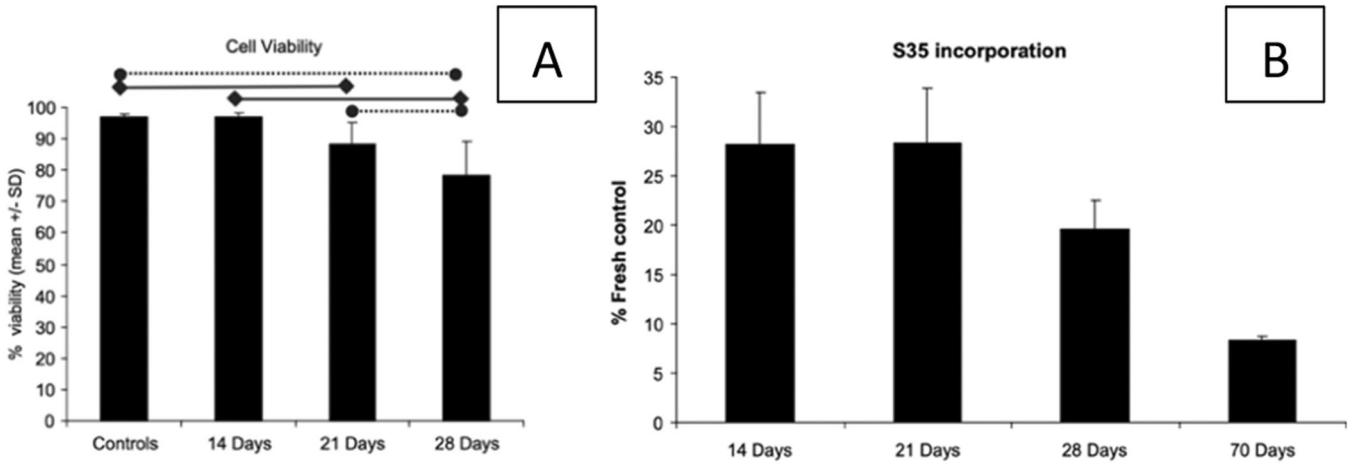

FIGURE 1 | (A) Cell viability presented as a percentage of living cells ($p < 0.05$ = solid line; $p < 0.001$ = dashed line). (B) Data is presented as a percentage of 35S incorporation compared to fresh control. Figure 1 has been reproduced from Williams et al. [7] with permission of the publisher.

to reduced clinical utilization of RFE devices adjacent to cartilaginous surfaces in both arthroscopic and open procedures.

Thermal energy is also generated when using power devices such as a saw or reamer during OCA harvest. In an effort to further reduce the negative impact of thermal energy on chondrocyte viability, we developed a technique to reduce thermal energy associated with OCA plug harvest. Traditionally, bulb irrigation was used to limit thermal necrosis during plug harvest with powered devices. Further work demonstrated that chondrocyte viability is improved when the graft is submerged in saline relative to traditional bulb irrigation (72% whole plug chondrocyte viability with graft submersion vs. 61% whole plug chondrocyte viability with bulb irrigation, $p = 0.003$; unpublished data) [13, 14] (Figure 3A–C). Another recent study supported the use of cold irrigation and demonstrated no difference between using the ream and drill modes for graft harvest [15]. Consequently, we now harvest OCA plugs with the allograft completely submerged in saline under drill mode for maximal efficiency.

2.3 | Removal of Immunogenic Elements

An area of concern with the use of allograft tissue is an antibody-based immunogenic response which may impact graft integrity and longevity. To investigate the effectiveness of various lavage techniques in removing immunogenic elements believed to be present in the donor marrow, 18 OCA plugs were harvested from 6 fresh human hemicondyles (15-mm diameter, 6-mm depth) and randomized to three treatment arms: (A) No lavage; (B) 1 L standard saline lavage; (C) Simultaneous saline (1 L) and 1-min high-pressure CO_2 lavage [16]. A "percentage fill" of remaining marrow elements in the superficial, middle, and deep zones was then quantified. Both lavage groups performed significantly better in evacuating remaining marrow elements in the superficial and middle zones; however, lavage and high-pressure CO_2 performed significantly better in evacuating marrow elements from the deep zone. As a result of these findings, surgeons maintain a graft depth of 5–8 mm to limit antigenicity and possible cyst formation which is associated with increased amounts of subchondral

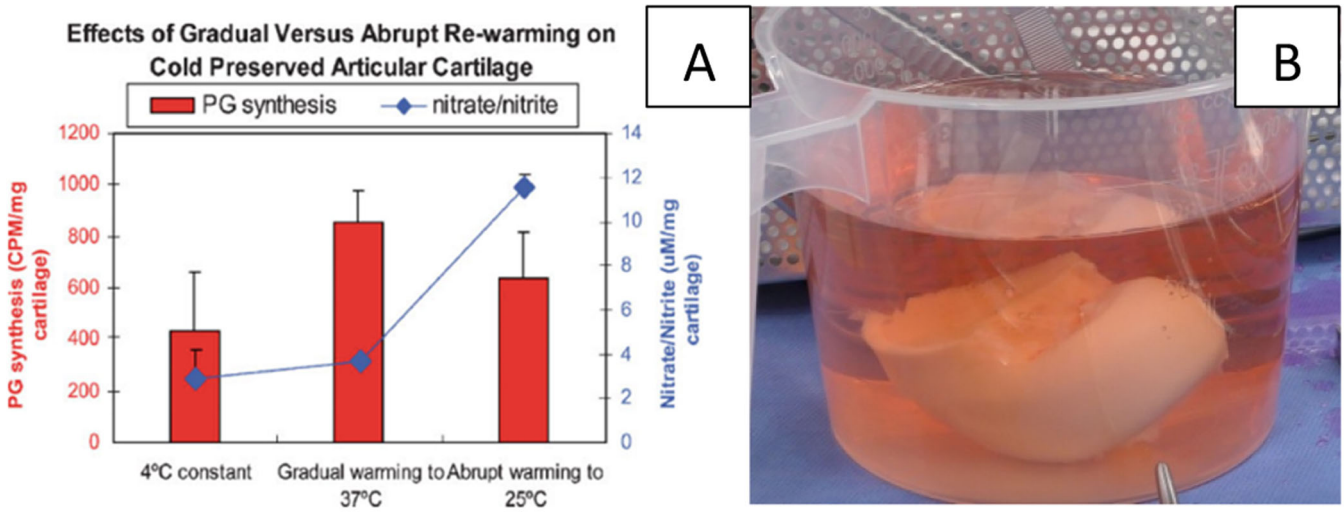

FIGURE 2 | (A) Gradual versus abrupt rewarming of cold preserved bovine cartilage plugs. (B) Image of a fresh, cold-preserved osteochondral allograft gradually rewarmed in room temperature saline to optimize metabolic activity. Figure 2A has been reproduced from Pylawka et al. [8] with permission of the publisher. Figure 2B has been reproduced from Allahabadi et al. [14] under the Creative Commons license.

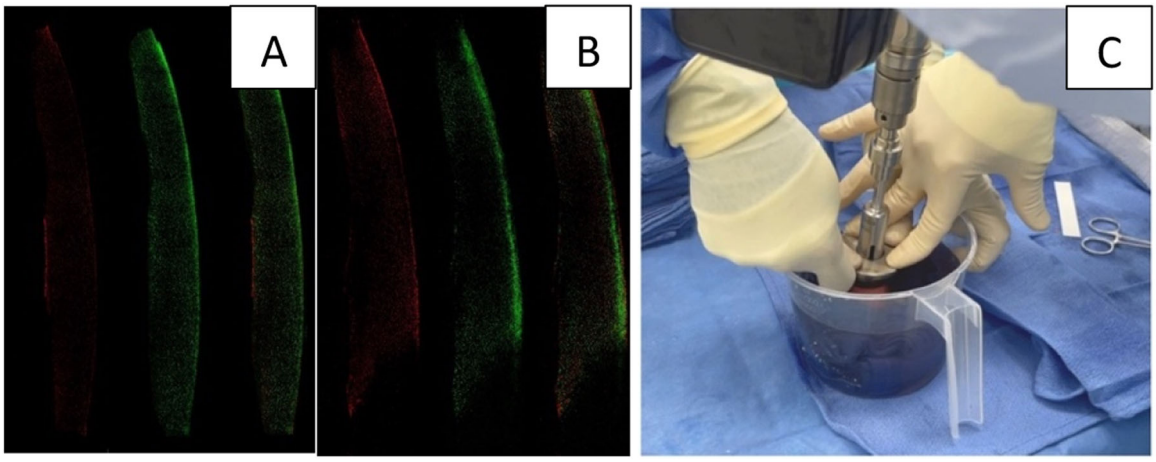

FIGURE 3 | (A) Live/dead staining demonstrating chondrocyte viability (green) using bulb irrigation (61%). (B) Live/dead staining demonstrating chondrocyte viability (green) with submerged harvesting (72%). Figure 3A,B has been reproduced from Elias et al. [13] with permission of the publisher. (C) An OCA plug is harvested with the reamer on drill mode while the whole allograft is submerged in saline to preserve chondrocyte viability. Figure 3C has been reproduced from Allahabadi et al. [14] under the Creative Commons license.

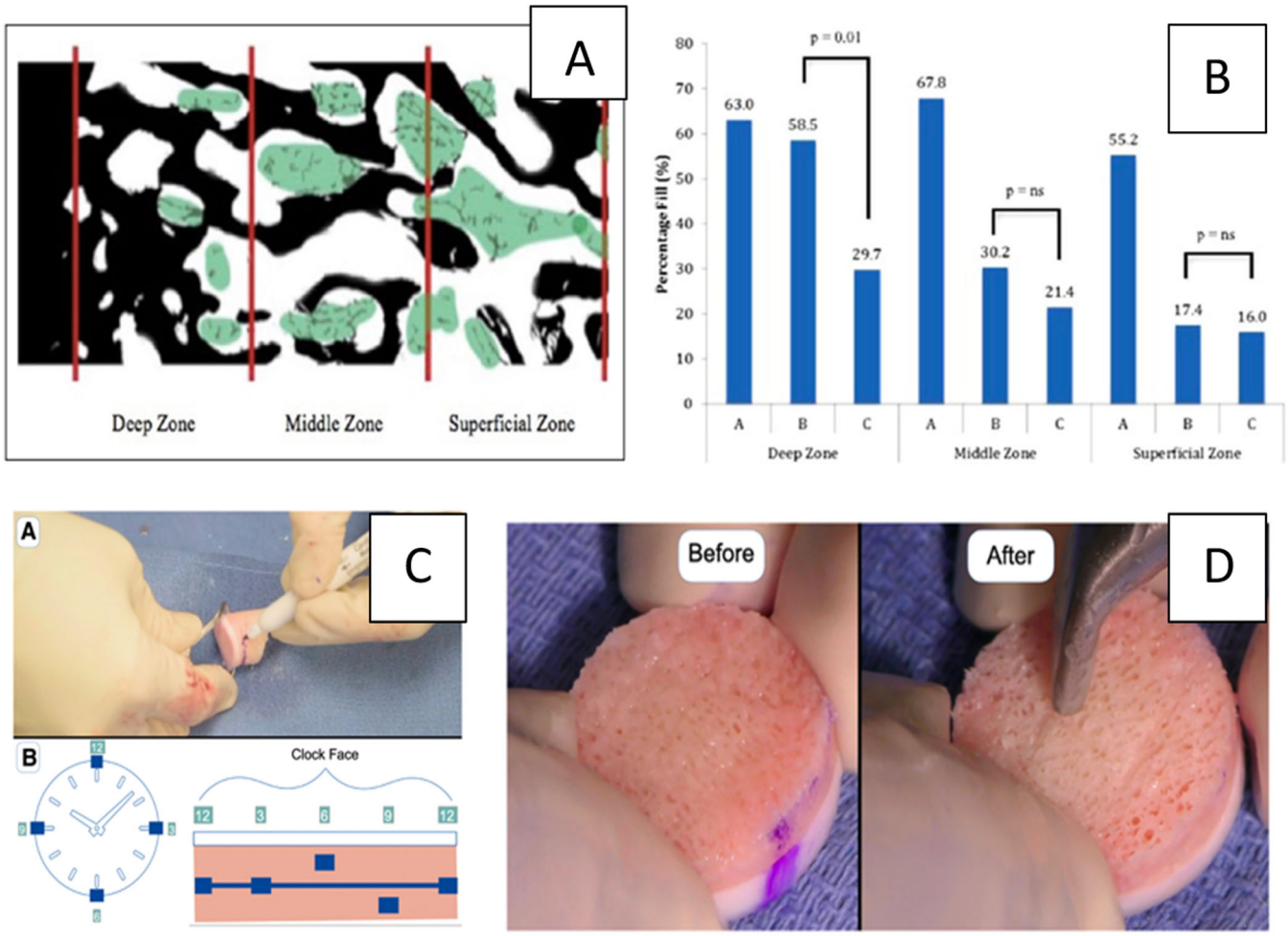

FIGURE 4 | (A) Illustration of decalcified OCA histology showing bone (black), trabecular space still containing marrow elements (green), and trabecular space that has been washed free of marrow elements (white). (B) Marrow elements remaining did not differ between treatment groups in the superficial or middle zones (Column A and B, respectively). However, a combination of saline and high-pressure CO_2 lavage nearly halved the amount of remaining marrow elements in the deepest zone of the OCA transplant (Column C). (C) Our technique for marking plug depth (image C-A) The plug is oriented and the desired depth is marked. (Image C-B) Care is taken to understand how the depth of the plug may vary in each of the 12, 3, 6, and 9 o'clock positions for proper orthogonal graft placement. (D) Pressurized CO_2 is applied to the subchondral bone to further reduce immunogenic marrow elements throughout the subchondral bone depth after saline pulsed lavage. There is often a visual change in color from before (left) and after (right) use of pressurized CO_2 with visual improvement in porosity. Figure 4A,B has been reproduced from Meyer et al. [16] with permission of the publisher. Figure 4C,D has been reproduced from Allahabadi et al. [14] under the Creative Commons license.

bone and remaining marrow elements. Furthermore, following saline lavage, many surgeons utilize a specialized device to provide high-pressure CO_2 to deep clean the subchondral bone during graft preparation (Figure 4A–D).

2.4 | Orthobiologics to Augment Allograft Integration

To improve allograft osteointegration, we postulated that bone marrow aspirate concentrate (BMAC) may decrease immunogenicity by introducing autologous cells within the osseous portion of the OCA plug. To evaluate this, a prospective randomized single-blind trial was performed comparing OCA transplantation in patients who underwent a sham BMAC harvest to patients whose OCA plugs were soaked in BMAC [17]. Preliminary results of 36 patients demonstrated the BMAC group to have less pain at 1 year postoperatively as reflected by the Western Ontario and McMaster Universities Arthritis Index (WOMAC). Furthermore, the number of larger postoperative cystic changes (> 3 mm in size) as measured by CT scan was reduced in those grafts hydrated with BMAC at 6 months which is believed to be associated with reduced graft failure. Consequently, we offer all our OCA candidates the option to consider the addition of BMAC to their OCA transplantation procedure (Figure 5A–C).

In a separate laboratory collaboration, we found high-pressure CO_2 to better remove moisture and increase graft porosity leading to greater BMAC saturation and uptake optimizing graft biology and subsequent bone integration [18] (Figure 6).

2.5 | Donor-Recipient Topography Matching

We completed a series of anatomic matching studies, the most recent of which is the basis of a National Institute of Health

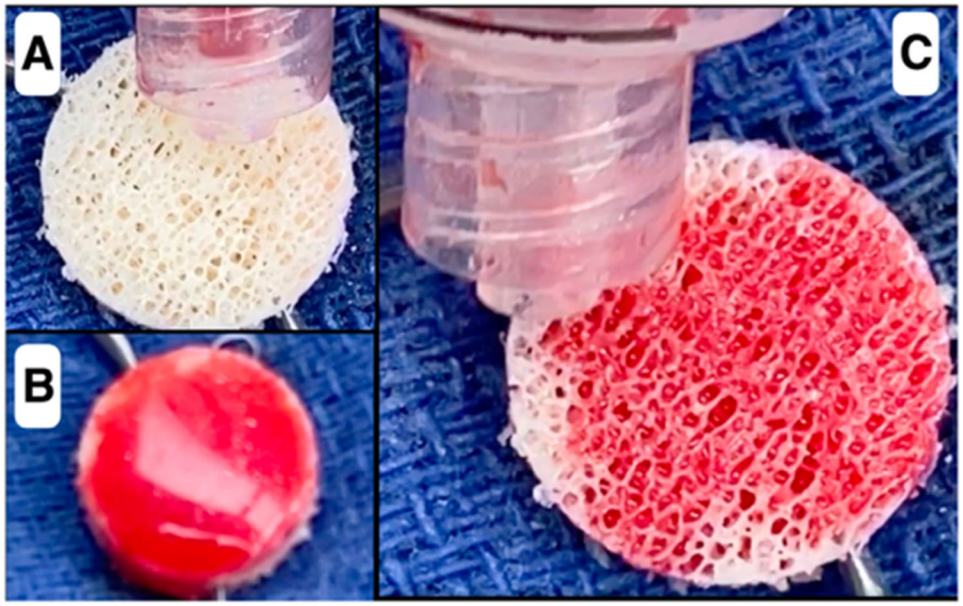

FIGURE 5 | After pulsed lavage and pressurized CO_2, the graft is better prepared for orthobiologic application. BMAC further reduced large cysts formation and decreased the rate of subsequent surgeries. (A) Before application of BMAC to the subchondral bone prepared with pulsed lavage and pressurized CO_2. (B) After the application of BMAC to the subchondral bone that was not prepared with pressurized CO_2. There is less fluid uptake within the graft. (C) After application of BMAC applied to subchondral bone that was prepared with both pulsed lavage and pressurized CO_2. There is more uniform uptake and fluid volume within the graft. Figure 5A–C has been reproduced from Allahabadi et al. [14] under the Creative Commons license.

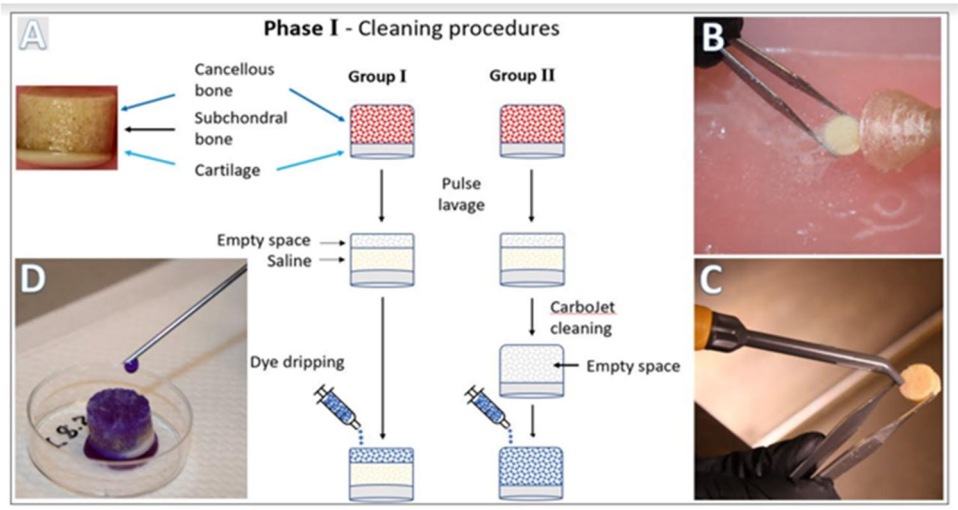

FIGURE 6 | (A) Schematic flow-chart of Phase I featuring the harvested plug positioned with the cartilage surface facing downwards. (B) Pulse lavage cleaning. (C) CO_2 (CarboJet device) deep cleaning. (D) Application of die dripping utilizing a 2cc solution of 440 μM Resazurin to mimic BMAC application. Figure 6 has been reproduced from Atzmon et al. [18] with permission of the publisher.

(NIH) grant to further our investigations. Matching the anatomic 3-dimensional (3D) curvature of the original cartilaginous surface being restored is a procedural objective believed to be important in reconstructing the native architecture of the knee. Accurate matching between the recipient and donor can be challenging, particularly for OCA transplantation of larger irregular-shaped defects as well as lesions involving the trochlea and patella. Traditionally, single 2D anatomic factors such as tibial width was used by graft agencies to provide "matching" allografts. To improve upon this, we explored graft topography to best match recipient anatomy to potentially expand the available donor pool and to address general concerns for graft availability. A study using computer-simulation was developed to assess the topographic matching of a lateral femoral condyle (LFC) donor OCA to a medial femoral condyle (MFC) recipient defect [19]. Cadaveric hemicondyles were used to construct 3D computerized tomography (CT) models to assess topographic matching. The findings suggested that the mean least distance of the articular cartilage surface was < 0.5 mm in all donor recipients and that there was no significant difference among donor groups. The conclusions were that ipsilateral and contralateral LFC donor tissue can be used for MFC lesion grafting significantly increasing the possible donor pool.

Large and irregular chondral defects create a unique complexity in topographic matching during surgery as they often require an oblong-shaped OCA or overlapping grafts (commonly referred to as the "snowman technique"). To explore ways to mitigate this challenge, a computer-simulated model was developed to assess the topographic matching of oblong OCAs to treat large oval MFC lesions [20]. The results suggested that oblong MFC donor grafts are acceptable to treat large oval MFC lesions. However, oblong LFC donors may result in increased peripheral step-off and surface mismatch. Another study with a similar design was performed to quantify cartilage and subchondral surface topography mismatch for oblong and overlapping allografts [21]. Our findings demonstrated that overlapping allografts provide superior and more reliable articular cartilage surface topography matching compared to oblong allografts. Moreover, a subsequent study with a similar methodology was used to identify anatomic factors needed for optimal matching of trochlear defects and subsequent transplantation [22]. We found that sagittal angle, sulcus angle, and lateral radius of curvature mismatch should be used to determine optimal donor trochlear OCAs, particularly in the setting of large (30-mm) central lesions. Lastly, a similar study was completed to evaluate patellar topographic matching and found that patellar cartilage width and facet length are key anatomical components for optimizing topographic matching [23]. These studies have significantly increased the allograft donor pool and are now transforming preoperative and intraoperative donor-recipient topographic matching algorithms (Figure 7A,B). To further this body of work, we are currently investigating the use of 3D-printed patient-specific guides for OCA transplantation [24] (Figure 8A,B).

Recently, we explored newer imaging technologies that allow for immediate 3D modeling using iPhone-based cartilage topography scanning. These technologies may allow the implementation of augmented reality (AR) tools intraoperatively to assist the surgeon in selecting the exact location to procure an OCA plug to most accurately match the recipient site. Recently, we completed a novel feasibility study to evaluate the accuracy of 3D iPhone scans using commercially available applications compared to CT for mapping the chondral surface topography of the knee [25]. We found minimal differences between a 3D iPhone scanning application and conventional CT scanning when analyzing surface topography. While still in its infancy, this technology harbors the potential to further optimize graft matching and minimize the related anatomic variability and surgical complexity.

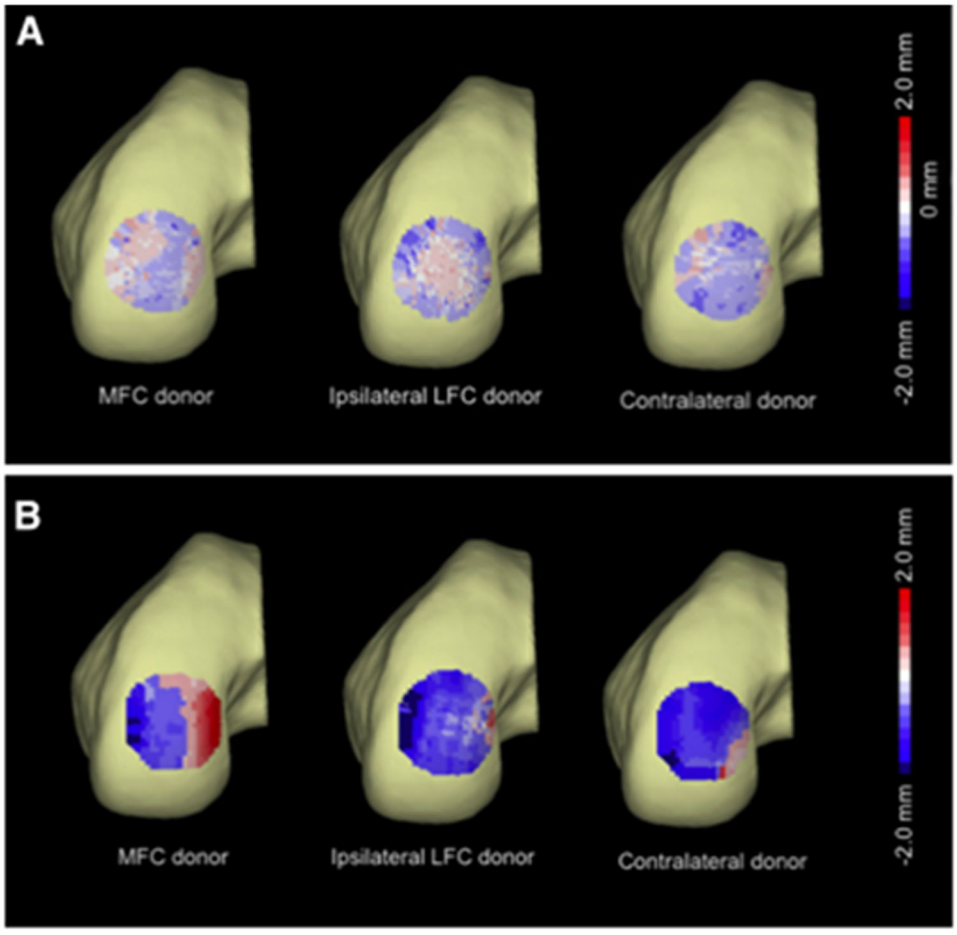

FIGURE 7 | (A) 3D-dimensional representation of the distance distribution of the cartilage surface of a graft model superimposed on a medial femoral condyle. The blue gradient color represents penetration into the defect model, whereas red represents prominence. The white color indicates perfect congruence between the defect and the graft models. (B) A 3D representation of the distance distribution of the resulting subchondral bone surface of a similar model. Figure 7 has been reproduced from Urita et al. [19] with permission of the publisher.

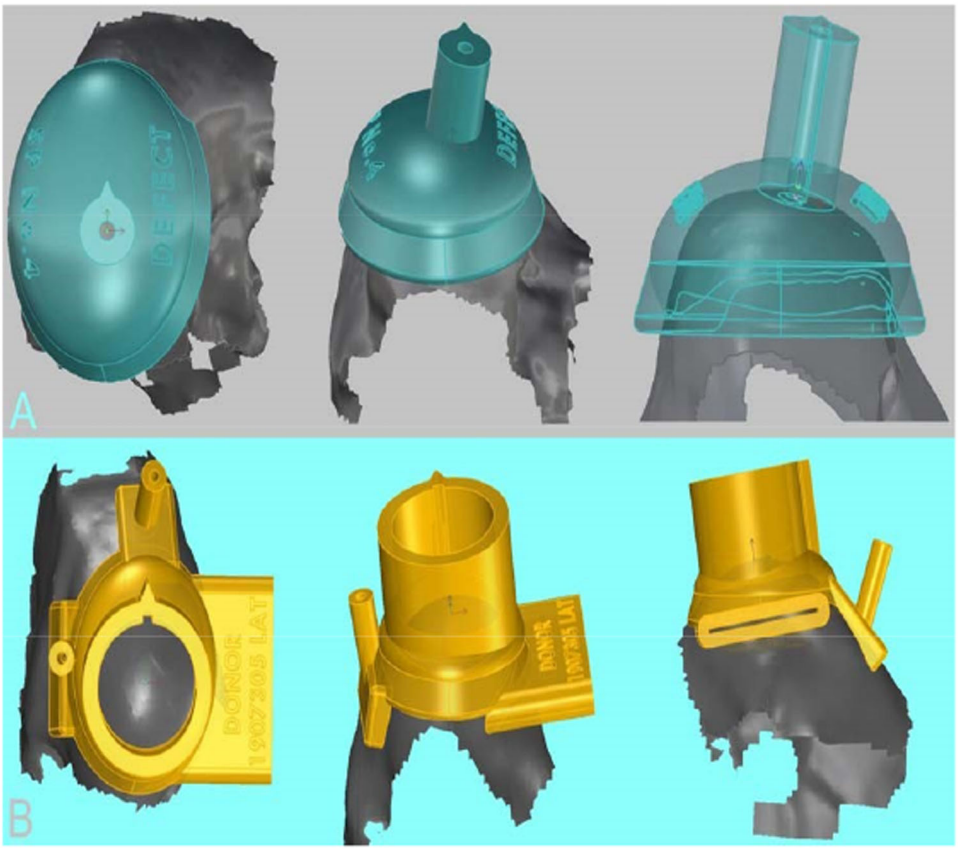

FIGURE 8 | (A) Patient-specific guides for defect creation. (B) The patient-specific guides may accommodate a hole saw at the location of the plug calculated from in-silico analysis and a slit for a predetermined depth cut. Figure 8 has been reproduced from Elias et al. [117] with permission of the publisher.

2.6 | The Impact of Allograft Impaction

Traditionally, press-fit insertion of OCA plugs required impaction with a relatively high repetitive force. To assess the effects of impaction on cell viability, we performed a cadaveric study in which bovine OCA plugs were implanted using a plastic tamp device fitted with a load cell [26]. We found that during insertion, the force was 25 ± 6 N and increased with time to a peak of 307 ± 84 N. Assessment of cell viability at 48 h and 7 days of tissue culture identified cell death to be 60% in the upper zone and 20% for the middle and deep zones. Cell death was significantly higher in all zones in the impacted group. A follow-up study using 96 OCA plugs harvested from the trochlea of bovine stifle joints also demonstrated that impulse magnitude has a direct detrimental effect on cell viability [27]. A complementary controlled laboratory study hypothesized that under constant impulse conditions, higher impaction loads would be more detrimental to cell viability, matrix integrity, and collagen network organization resulting in proteoglycan loss and NO release [28] (Figure 9A–C). Osteochondral explants from bovine trochleae were subjected to a series of consistent impaction loads. We found that impacted OCA plugs had significantly lower cell viability compared to nonimpacted plugs and that there was a dose-response relationship in loss of cell viability with respect to load. An additional study compared the effect of impaction and proinflammatory cytokines on prolonged refrigerated OCA and fresh human cartilage [29]. In this study, we found impaction load to create a greater detrimental effect on cell viability in refrigerated OCAs compared to fresh cartilage. Moreover, the addition of proinflammatory cytokines decreased OCA metabolism and integrity even further.

To avoid traumatic impaction and ease insertion, the edges of the bony layer of the graft are now chamfered. We also place several small grooves within the bone to facilitate graft insertion and increase access to deep subchondral bone. Based on the above laboratory work we now recommend graft insertion with no more than thumb pressure. We also use a rescue suture behind the graft to facilitate removal and repositioning if needed (Figure 10A,B).

2.7 | Salvage of Contaminated Allografts

Contamination of an OCA before implantation may occur with inadvertent graft mishandling in the operating room. While such events may be rare, the consequences of contamination of an OCA can be devastating. Cleansing protocols should not only successfully eliminate all possible contaminants, but also preserve cell viability in the case of a fresh OCA. A controlled laboratory investigation was therefore set forth [30]. OCA plugs were subjected to pulse lavage with 1-L solutions of 0.002%, 0.01%, 0.05%, and 0.25% chlorhexidine gluconate (CHG) and cultured for 0, 1, 2, and 7 days in media of 10% fetal bovine serum and antibiotics. LIVE/DEAD Viability Assay showed solutions of > 0.002% CHG significantly decrease cell viability. Afterwards, a comparison of 4 groups of osteochondral plugs was performed; a non-contaminated group and three groups contaminated by *Staphylococcus aureus* which received either no treatment, saline pulse lavage, or 0.002% CHG. Contaminated OCA plugs treated with 0.002% CHG demonstrated no colony-forming units. Thus, in case of graft contamination, pulse lavage with 0.002%

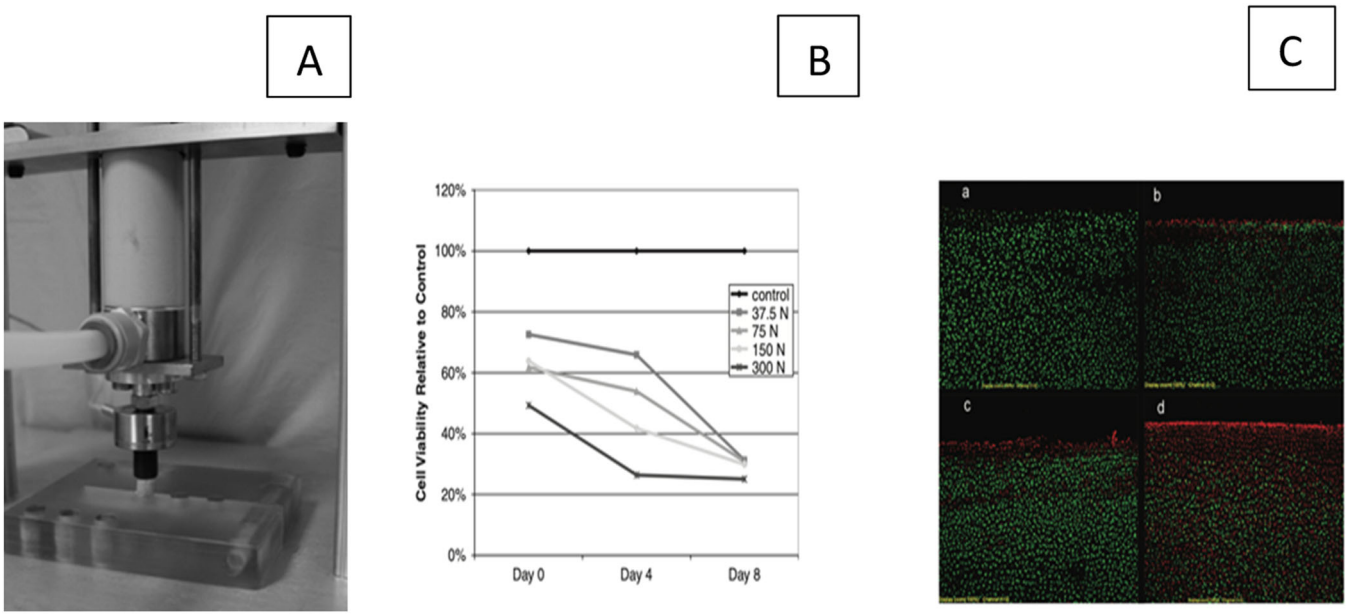

FIGURE 9 | (A) Pneumatic impaction device (SmartImpactor, Chicago, Illinois) used to impact OCA plugs with consistent loads. (B) Graphical depiction of mean cell viability at different loading levels over time. (C) Cell viability at day 0 for different load levels: A, control; B, 75 N; C, 150 N; and D, 300 N. Note the increasing spread of cell death into deeper tissue levels. Figure 9 has been reproduced from Kang et al. [28] with permission of the publisher.

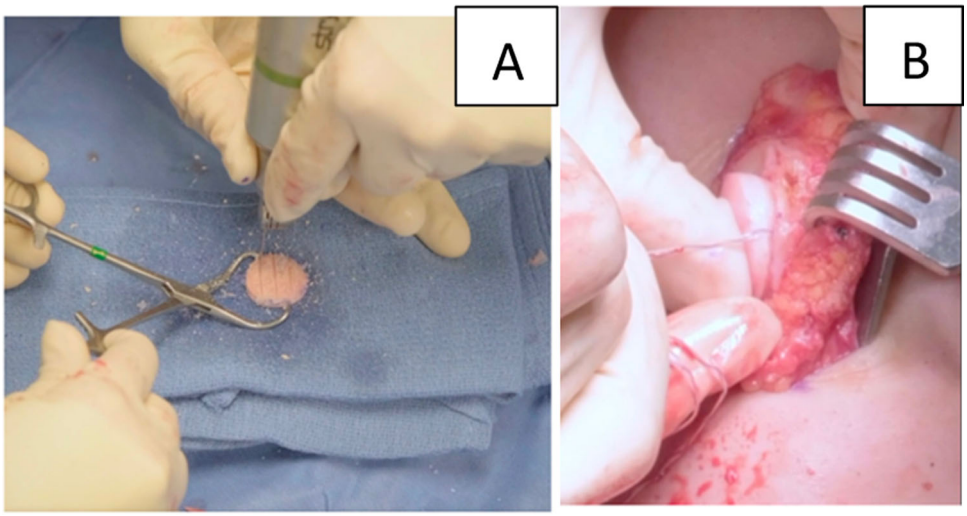

FIGURE 10 | (A) The bone is prepared with a small oscillating saw. The edges of the bone may be chamfered to ease graft insertion. The authors place several small grooves within the bone to facilitate graft insertion and increase access to deep subchondral zones. (B) A rescue suture is placed behind the graft to allow for better graft control and to facilitate of graft removal if necessary for repositioning.

Chlorhexidine can be used to sterilize the graft without adverse effects on cell viability (Figure 11A–H).

To summarize, graft preparation and surgical recommendations for OCA transplantation are presented in Table 1.

3 | Focal Cartilage Defects Symptomatology and Imaging

Before indicating a patient for OCA transplantation, a thorough evaluation of the patient's history, physical examination, and imaging is critical. As such, we have published what has become an evidence-based approach in various forums [1, 4, 31–41]. In some cases, focal cartilage defects may represent a point in time on the spectrum of early knee osteoarthritis. To better understand the symptomatology of patients with focal cartilage defects compared to patients with knee osteoarthritis, we compared patients between the ages of 18–55 undergoing OCA transplantation versus total knee arthroplasty (TKA). We found patients with knee osteoarthritis scheduled for a TKA to have more severe symptoms, particularly medial-sided pain and knee swelling with pain associated with knee straightening and while standing upright and rising from a sitting position [42]. These symptoms, which we regard clinically as a "wet knee," further strengthened our notion that these patients might be more difficult to treat with less predictable outcomes following cartilage restoration procedures.

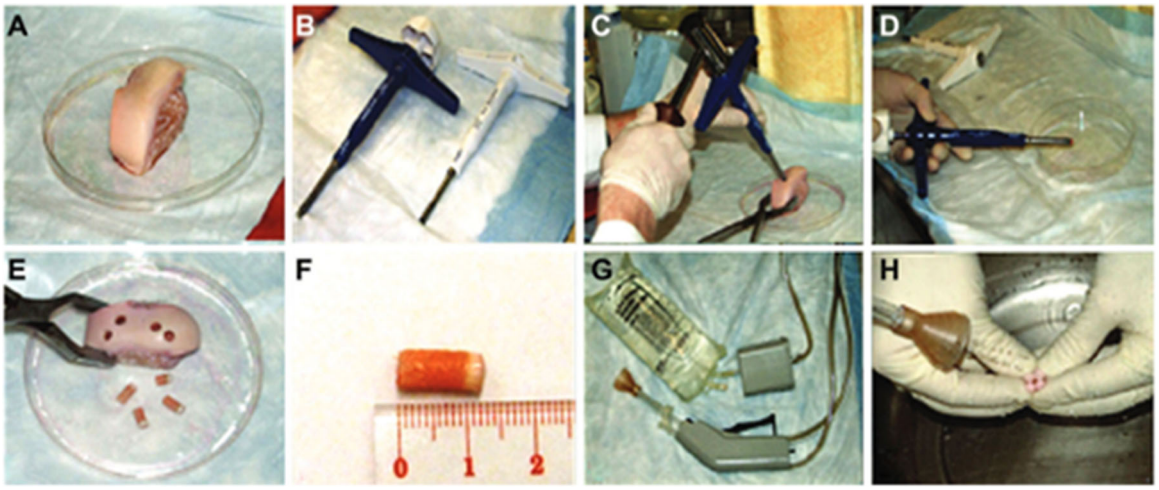

FIGURE 11 | (A) Femoral hemicondyle. (B) Osteochondral autograft transfer system harvesters. (C) Graft harvest. (D) Plug removal using core extruder. (E) Hemicondyles with osteochondral plugs. (F) Osteochondral plug. (G) Pulse lavage system with saline. (H) Pulse lavage of osteochondral plugs. Figure 11 has been reproduced from Campbell et al. [30] with permission of the publisher.

TABLE 1 | Graft preparation and surgical recommendations for osteochondral allograft transplantation.

Category	Recommendation	Evidence/rationale
Graft preservation	Use of grafts with storage up to 28 days at 4°C	Cell viability maintained at > 65%–90% at 28 days
Graft rewarming	Gradual rewarming (4° → 25° → 37°)	Minimizes loss of chondrocyte metabolic function
Thermal management	Avoid radiofrequency devices near cartilage surfaces	RFE creates significant chondrocyte death
Graft harvesting	Harvest with graft completely submerged in saline under drill mode	Improved chondrocyte viability (72% vs. 61% with bulb irrigation)
Marrow element removal and immunogenicity reduction	Maintain graft depth of 5–8 mm. Use saline pulsed lavage plus high-pressure CO_2	Better evacuation of marrow elements from deep zone. Limits antigenicity and possible cyst formation
Biological augmentation	Consider BMAC soaking of grafts	Reduced cystic changes > 3 mm and decreased pain at 1 year
Graft insertion	Use thumb pressure only, avoid impaction	Impaction significantly decreases cell viability (dose-response)
Graft preparation	Chamfer bony edges, create grooves in bone	Facilitates insertion and increases access to deep subchondral bone
Rescue technique	Place suture behind graft	Facilitates removal and repositioning if needed
Contamination management	Pulse lavage with 0.002% CHG if contaminated	Eliminates contaminants without adversely affecting cell viability

Magnetic resonance imaging (MRI) is the primary imaging tool used to diagnose focal cartilage defects. However, not all focal cartilage defects found on MRI are clinically meaningful. To evaluate this, we performed a study looking at 28 knee MRIs of asymptomatic National Basketball Association (NBA) players [43]. The results showed that abnormalities are prevalent in asymptomatic NBA players with abnormal signal/chondromalacia (50%), focal cartilage defects (7.1%), and subchondral bone marrow edema (25%) found in asymptomatic players. To establish the clinical meaningfulness of subchondral bone marrow edema (BME) in patients undergoing OCA transplantation, an additional study was designed and executed [44]. We found preoperative subchondral BME was present in 82% OCA transplantation patients. More severe BME and an increased involvement in the juxta-articular surface were correlated with reduced postoperative PROs. A larger area of BME was associated with an increased risk of clinical failure. Imaging of the articular cartilage of the knee is continuing to evolve with newer quantitative cartilage imaging techniques that include dGEMRIC (delayed gadolinium-enhanced MRI of cartilage), sodium-23 imaging, T1rho, T2*, and T2 mapping. These techniques are promising although their potential for routine clinical application remains unknown at this time [45]. An

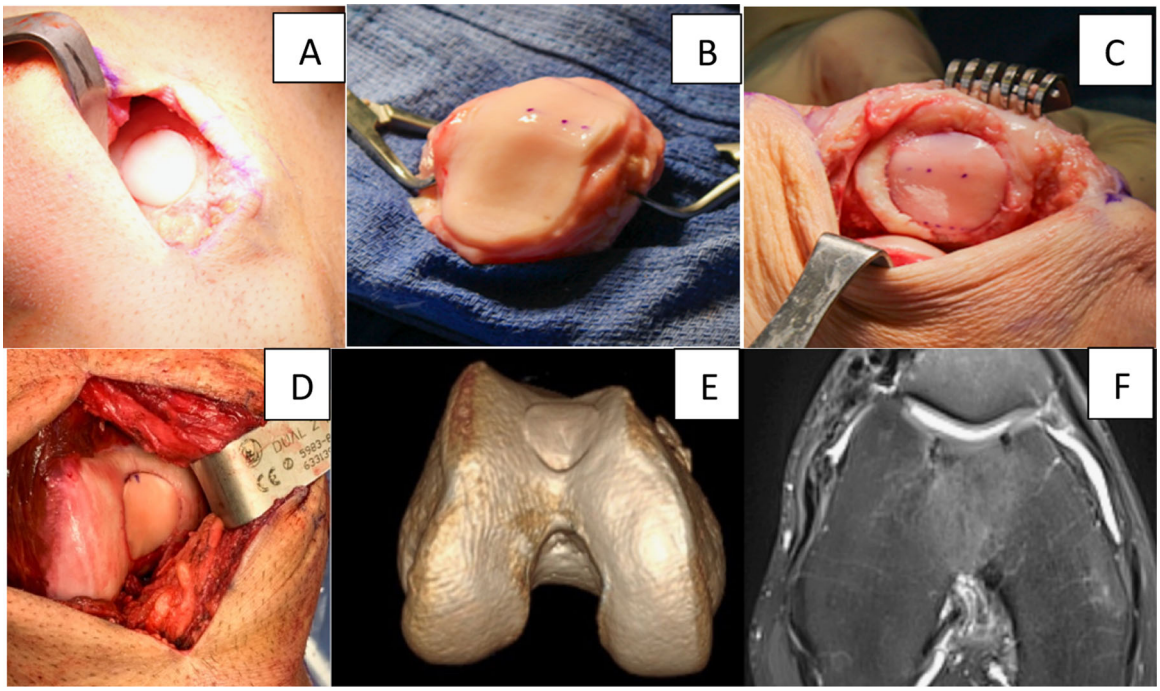

FIGURE 12 | (A) Completed OCA transplantation of the medial femoral condyle. (B) Donor patella. (C) Completed OCA transplantation of the patella. (D) Completed OCA transplantation of the trochlea. (E) Postoperative 3D CT reconstruction of the trochlea. (F) Postoperative axial MRI demonstrating anatomic integration of a trochlea OCA. Figure 12D has been reproduced from Dasari et al. [118] with permission of the publisher.

understanding of the impact of preoperative imaging signals is currently a topic of discussion with patients indicated for OCA transplantation to best manage clinical expectations.

4 | Evolution of the Surgical Technique and Educating Our Colleagues

Over the last 25 years, we published OCA surgical techniques to share knowledge and to provide pearls and pitfalls to complete a safe, successful, and reproducible operation (Figure 12A–F). As we continue to strive for evidence-based improvements, techniques have evolved with modifications published and presented on a regular cadence [14, 33, 35, 46–51]. We also developed single-use instrumentation for OCA harvest and transplantation which are now commercially available [52]. Furthermore, we share our 5-phase rehabilitation protocol as a publication [53] and online resource [54]. A soon to be published study demonstrating that immediate unrestricted weight-bearing following OCA transplantation to the distal femur is non-inferior to restricted protocols based on PROs [55]. This study will hopefully have a significant impact on traditional OCA transplantation rehabilitation enhancing the recovery timeline for future patients.

5 | The Effect of Proinflammatory Cytokines

As mentioned previously, proinflammatory cytokines decrease OCA tissue metabolism and integrity [29]. To further evaluate the effect of proinflammatory cytokines on clinical outcomes, a study assessed longitudinal concentrations of select synovial fluid biomarkers obtained by serial aspirations following cartilage restoration and their potential association with patient-reported outcomes (PROs) [56]. In this prospective study, aspirations were obtained intraoperatively and postoperatively at 2 weeks, 6 weeks, 6 months, and 1 year. Using multiplex ELISA, we found increases in MMP-1 and ACAN and a decrease in FGF-2 in the early postoperative period. We also found that an early increase in IL-1a levels at 2 weeks postoperatively was associated with worse Knee Injury and Osteoarthritis Outcome Score (KOOS) subscores at 6 months postoperatively (Figure 13).

6 | Clinical Outcomes Research to Optimize Patient Selection

Prospectively collecting clinical outcomes in an institutional database during the past 25 years enables frequent opportunities to answer new questions about the impact of our basic science work and clinical decision-making to continually assess and improve patient outcomes. There is also a need to define how to best evaluate patient outcomes following cartilage restoration procedures.

6.1 | Defining and Evaluating Imaging and Clinical Outcomes

We initially assessed the quality and responsiveness of legacy knee questionnaires such as the KOOS, International Knee Documentation Committee (IKDC) Subjective Knee Form, WOMAC, Modified Cincinnati Knee Rating System (CKRS), and Short Form 36 (SF-36) for patients with articular cartilage defects [57, 58]. We identified that the most commonly used outcomes metric, the IKDC, was as reliable and responsive as the other legacy questionnaires mentioned above [57]. We also evaluated the KOOS and found it to have excellent reliability

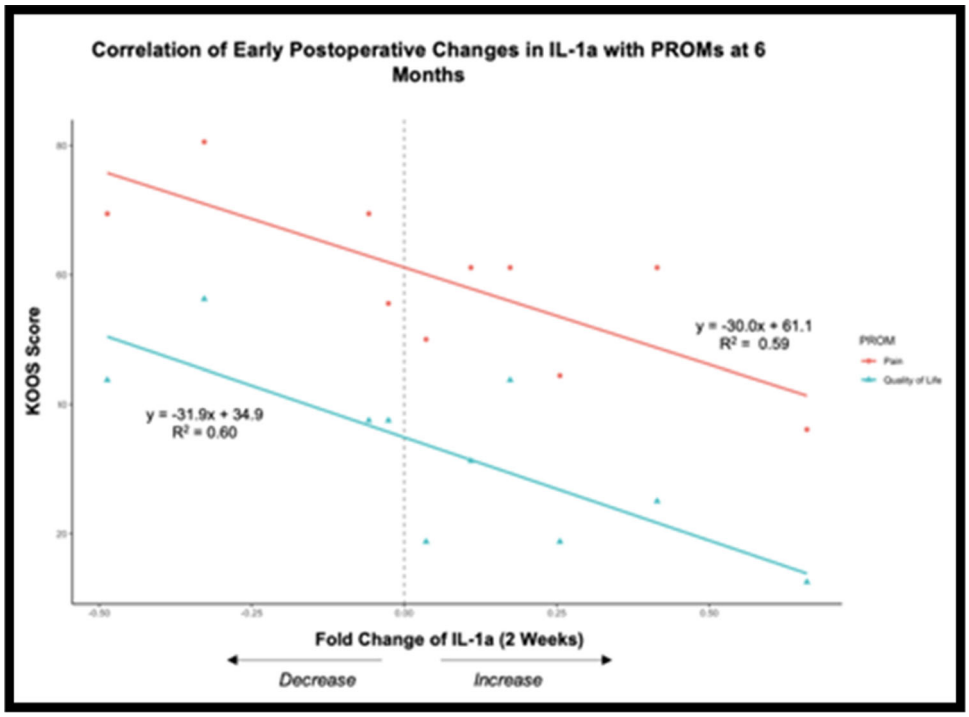

FIGURE 13 | Early postoperative change in IL-1a significantly correlates with KOOS pain and quality of life scores at 6 months, where a decrease in IL-1a was associated with better outcomes. Figure 13 has been reproduced from Dandu et al. [56] with permission of the publisher.

and responsiveness in patients with articular cartilage defects of the knee [58]. Today, IKDC and KOOS are likely the most common PROs used to assess outcomes following the treatment of patients with focal cartilage defects and are included as the standard PROs for FDA trials investigating new solutions for cartilage repair. Furthermore, we now define success and failure following articular cartilage surgery in clinical, histologic, subjective, and imaging-based terms [59].

We also looked into the methodology and comprehensiveness of studies reporting outcomes of patients treated with articular cartilage defects to improve our reporting ability [60, 61]. Subsequently, we developed the MARK score (Methodological quality of ARticular cartilage studies of the Knee) as is a valid and reliable knee articular cartilage condition–specific methodological instrument used frequently today to assess the quality of outcomes research [62].

As for imaging outcomes assessment, we found that radiographs demonstrate poor inter-rater reliability and accuracy in evaluation of healing after OCA transplantation of the knee. We found a high rate of missed cystic changes on radiographic analysis and poor correlation with CT scan findings [63]. As such, we do not routinely obtain advanced imaging to all our OCA transplantation patients, unless indicated.

6.2 | Evaluating Patient-Reported Outcomes, Failures, and Reoperations

Frequently, we utilize our cartilage database to study, present, and publish clinical outcomes and to determine independent variables associated with success and failure [64–68]. In a study of 160 patients undergoing OCA transplantation with a mean follow-up of 7.7 years, we found a sustained improvement in clinical outcomes with 5- and 10-year survival rates of 86% and 82%, respectively [65]. Notably, reoperations remain high at approximately 39.4% (Figure 14A,B). In a separate study, we also examined the clinically significant outcomes (CSOs) and defined the clinically important difference (CID) and patient-acceptable symptomatic state (PASS) following cartilage repair [69].

6.3 | Factors Associated With Clinical Outcomes

Multiple studies were completed to evaluate cardinal factors that may be associated with clinical outcomes following OCA transplantation. Examining the effects of age and sex, we found that patients ≥ 40 and < 40 do equally well in terms of complications, reoperations, and failures [70]. We found patients < 40 years old to have lower KOOS scores perhaps due to greater physical demands and expectations. Newer unpublished data at a minimum 5-year follow-up demonstrates that females have higher or comparable CSO achievement rates when compared to males. Additionally, the male sex was found to be associated with decreased odds of achieving CSOs for the IKDC score [71]. In a separate study assessing outcomes in adolescent patients undergoing OCA transplantation, we identified a significant increase in PROs and a relatively low failure rate (5.6%) [72]. Interestingly, patients with closed physes showed greater PRO improvement than those with open physes. In another study assessing graft-related factors, we found that not only the size of the defect is related to failure, but also, and perhaps more significantly, the defect size:condyle ratio more closely tracked potential clinical failure [73]. Additionally, graft survival appears to be most strongly influenced by donor age, while donor sex was not found to be predictive [74]. We have also looked into graft location with multiple studies separately

assessing femoral condyle, patellofemoral joint, and multifocal OCA transplantation [65, 75–77]. We found isolated single-plug OCA demonstrated superior outcomes compared to unicondylar, multiplug OCA. However, multifocal OCA still demonstrated favorable outcomes with PRO improvement and a low failure rate. Plug OCAs also demonstrated superior outcomes compared to shell allografts for the patellofemoral joint. Given this experience, we were asked to lead the expert consensus statement for the Metrics of Osteochondral Allografts (MOCA) group on the management of large chondral and osteochondral defects in the patellofemoral joint to understand the global generalizability of clinical experiences [78]. To summarize, patient-specific factors associated with outcomes of OCA Transplantation are presented in Table 2.

6.4 | Return to Sports

Given the high prevalence of sports-participation among our patients, we sought to explore return to play (RTP) outcomes at various levels and types of sports [79]. We reported on 13 competitive athletes who underwent OCA transplantation with a mean follow-up of 5.9 ± 2.5 years. The adjusted RTP was 10 patients (77%), at a mean of 7.9 ± 3.5 months [80]. A separate study of 15 professional athletes with a mean follow-up of 4.9 ± 2.2 years showed 11 (73%) patients were able to RTP at a mean of 1.22 ± 0.4 years with 10 athletes (67% of the total; 91% of those who returned) returning to play at the same level or higher compared to performance before their surgical intervention [81]. Our specific considerations for RTP

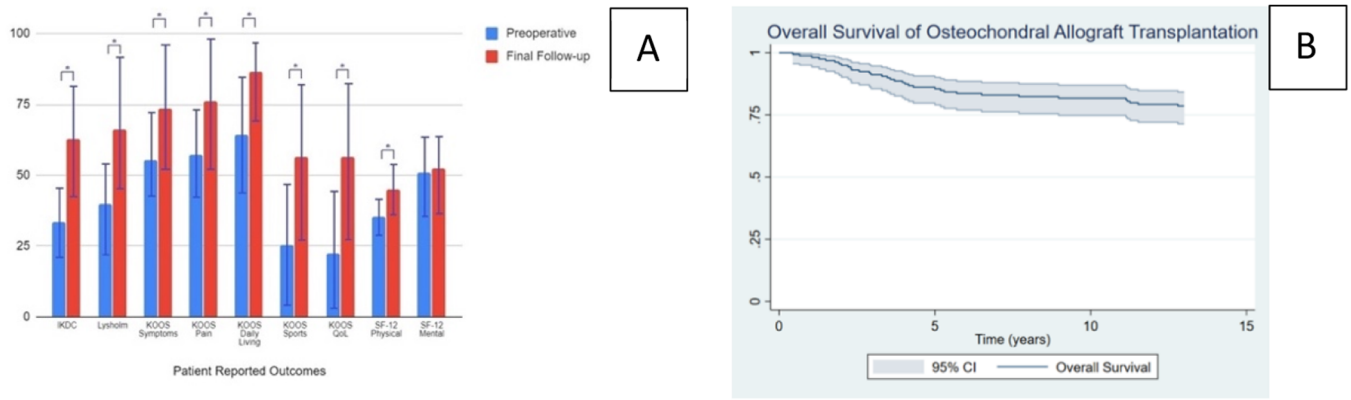

FIGURE 14 | (A) Preoperative and postoperative (final follow-up) PROs, including IKDC, KOOS, Lysholm, and SF-12 mental and physical subscales. (B) Overall Kaplan–Meier survivorship analysis. Survival probabilities following OAG at 1, 2, 3, 5, and 10 years were 98.7%, 95.6%, 91.2%, 86.2%, and 81.8%, respectively. Figure 14 has been reproduced from Gilat et al. [65] with permission of the publisher.

TABLE 2 | Patient-specific factors associated with outcomes of osteochondral allograft transplantation.

Factor	Finding/recommendation	Comment
Age	Patients ≥ 40 and < 40 do equally well	No difference in complications, reoperations, and failures
Adolescents	Significant increase in PROs with low failure rate (5.6%)	Patients with closed physes showed greater PRO improvement than those with open physes
Sex	Females have higher or comparable CSO achievement rates	Male sex associated with decreased odds of achieving CSOs for IKDC score
Defect size	Both absolute size and defect size:condyle ratio are important	Defect size:condyle ratio more closely tracks potential clinical failure
Donor factors	Donor age influences graft survival	Donor sex not predictive of outcomes
Graft configuration	Single-plug OCA superior to unicondylar, multiplug OCA	Multifocal OCA still demonstrates favorable outcomes
Location	Plug OCAs demonstrate superior outcomes compared to shell allografts	Particularly true for patellofemoral joint
Subchondral bone marrow lesions	Preoperative BMLs present in 82% of patients	More severe BMLs associated with reduced PROs and increased risk of failure
Concomitant procedures	Meniscal pathology and malalignment need to be address at time of surgery	Sustained PRO improvement observed in mid- to longterm follow-up with meniscal allograft transplantation and/or osteotomy
Failed prior procedures	OCA is effective after failed microfracture, ACI or primary cartilage procedures for OCD	Revision OCA transplantation has similar outcomes to primary OCA transplantation

following OCA are published along with separate considerations to address return to active military duty in this unique high-demand population [53]. Understanding the ability of individuals who desire to function at the highest level with reduced pain and improved performance is paramount to generalizing anticipated outcomes in lower demand, but more typical of patients who present for definitive surgical treatment for their symptomatic cartilage defects.

6.5 | Concomitant Procedures

Concomitant pathology and surgical procedures play a vital role in improving PROs and OCA graft survival [82–88]. Using our cartilage database, we identified that approximately 60% of OCA transplant patients underwent at least one major concomitant procedure including lateral meniscal allograft transplantation (MAT) (25%), medial MAT (20%), high tibial osteotomy (HTO, 10%), distal femoral osteotomy (DFO, 10%), tibial tuberosity osteotomy (2%), anterior cruciate ligament reconstruction (3%) and medial patellofemoral ligament reconstruction < 1% [65]. Multiple outcomes studies of OCA transplantation combined with MAT demonstrated significant improvement in PROs and graft survivorship of 86% at 5 years postoperatively [70, 89–93]. The authors recommend concomitant corrective osteotomy in patients with a mechnical axis that falls within the affected compartment, typically > 3–5 degrees of malalignment. When looking at our patients who underwent HTO, we found that patients who also underwent OCA transplantation were at a decreased risk for failure, but the likelihood of achieving minimal clinically important difference (MCID) or PASS was not significantly different [94, 95]. Furthermore, 80% of patients who underwent concomitant HTO and OCA transplantation returned to sports at an average of 11.4 ± 6.4 months postoperatively [96]. We also describe the clinical outcomes of patients who underwent concomitant DFO and OCA transplantation with a mean of 7-year follow-up and demonstrated an 89.5% survival rate with improved PROs [97]. These findings emphasized the importance of looking at all facets of knee pathology when considering cartilage restoration surgery to minimize failure and improve outcomes of this complex patient population (Figure 15A,B).

6.6 | Competing Procedures and Secondary OCA Transplantation

We examined multiple alternative cartilage restoration procedures as separate cohorts and in comparison to primary or secondary (OCA following the failure of a non-OCA procedure) OCA transplantation [98–101]. In an investigation of 359 patients, we found OCA transplantation following a failed microfracture procedure to yield similar outcomes to primary OCA transplantation and ACI [98]. We also found OCA transplantation to be effective in improving PROs following a failed ACI procedure [102] (Unpublished data). An additional study demonstrated successful outcomes with secondary OCA transplantation following a failed primary cartilage procedure in the setting of osteochondritis dissecans (OCD) [67]. More recently, we developed a score to estimate the risk of early patient election to pursue cartilage transplantation after chondroplasty and debridement which was found to be associated with preoperative AMADEUS (Area Measurement And DEpth Underlying Structure) grade, condylar involvement, KOOS, and VR-12 [9].

6.7 | Revision OCA Transplantation

While uncommon, revision OCA transplantation is a viable treatment option for failed primary OCA transplantation. In 2015, we published outcomes of revision OCA transplantation in 9 patients with a 4.5 ± 3.17 years follow-up [103]. Only one patient underwent subsequent total knee arthroplasty, representing an 11% overall failure. More recently we compared outcomes of primary and revision OCA transplantation. Fifteen revision OCA transplantation patients were compared to a matched cohort of 30 primary OCA transplantation patients. A concomitant procedure was performed in 73% of revision OCA transplantation patients. With an average 9.3 ± 3.0 years follow-up, there were no differences in PASS, graft survivorship free from reoperation, or failure between revision and primary OCA transplantation patients [104]. (unpublished data) To summarize, for select complex patients with a failed OCA transplant, revision OCA transplantation is an excellent treatment option, but it is imperative to ascertain the primary cause for failure and utilize concomitant procedures as indicated.

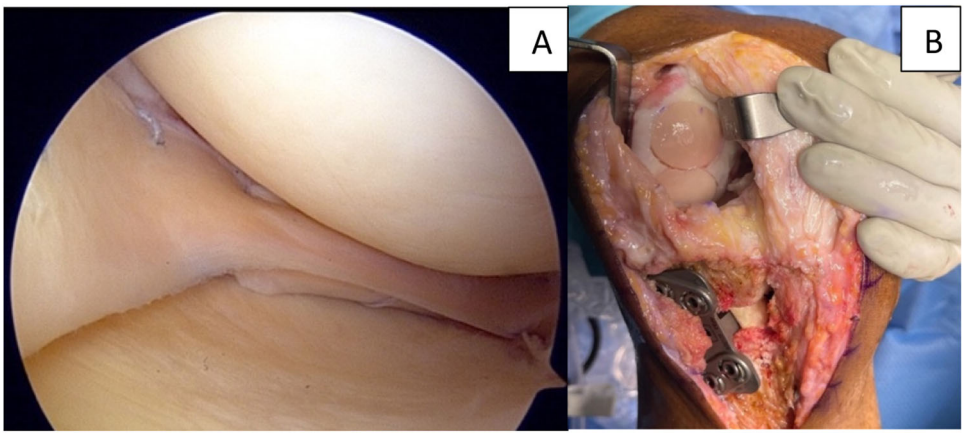

FIGURE 15 | (A) Arthroscopic image of a meniscal allograft transplantation (MAT). (B) Image of a completed concomitant "snowman" OCA and open-wedge HTO. Figure 15A has been reproduced from Haunschild et al. [119] under the Creative Commons license.

6.8 | Algorithms for Clinical Decision-Making

Critically examining our clinical outcomes led to the development of treatment algorithms to assist in clinical decision-making. The algorithms development began by incorporating factors associated with clinical outcomes, ultimately suggesting which cartilage procedures are more likely associated with a higher likelihood of success [105–114]. Based upon all of the previously described data, our algorithms include patient-specific factors as well as defect-specific factors such as patient physical demand, defect size and location, and consideration for the treatment of concomitant pathology. These algorithms have

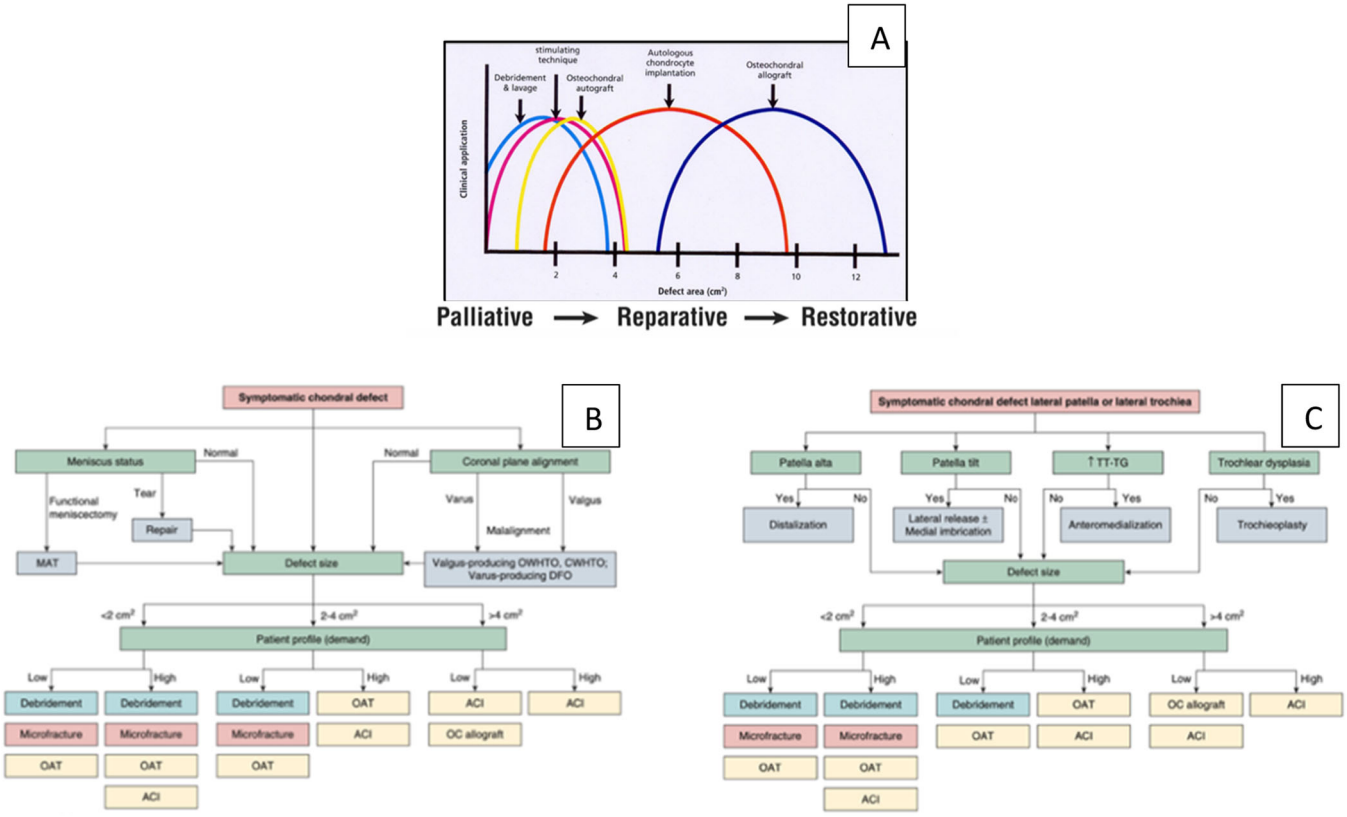

FIGURE 16 | (A) Phaseshift diagram emphasizing overlapping indications for treatment options when size alone is considered. More "granular" decision-making algorithms incorporating lesion location, size, patient demand, and the need for concomitant procedure for (B) the tibiofemoral joint and (C) the patellofemoral joint. Figure 16A has been reproduced from Cole and Farr [105] with permission of the publisher.

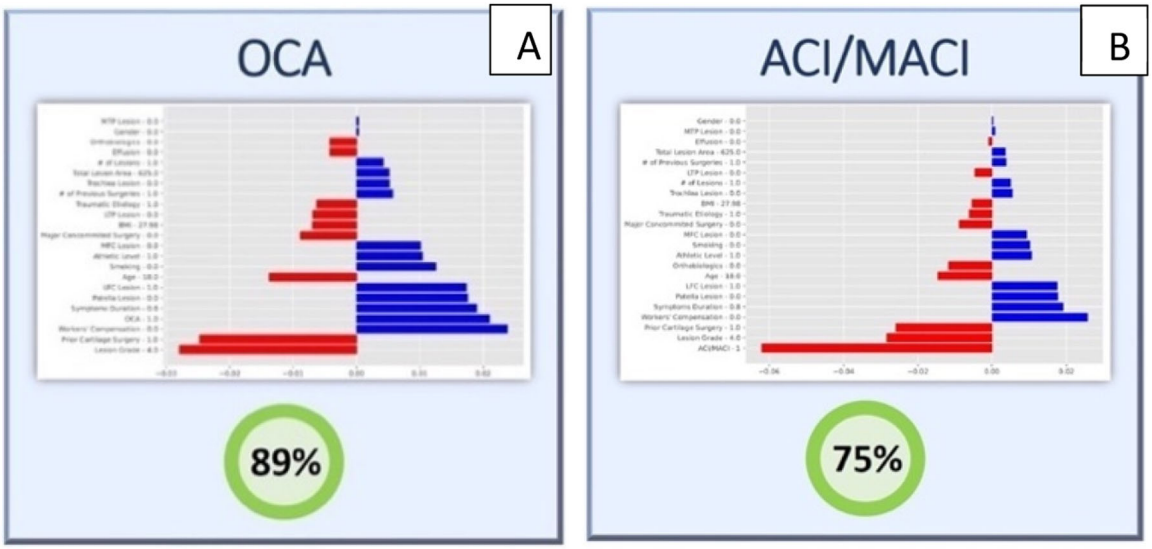

FIGURE 17 | (A and B) Patient-specific analysis and propensity to succeed for an 18-year-old male, BMI = 28, non-smoker, recreational athlete, one prior cartilage procedure, no worker's compensation, 8-months duration of knee pain without effusion following a traumatic injury, and a Grade 4, 25 × 25 mm lateral femoral condyle lesion. Figure 17B–C has been reproduced from Christian et al. [113] with permission of the publisher.

been refined and published over time as a resource for clinical practice guidelines (Figure 16A–C).

Recently, we published our evidence-based machine learning algorithm which takes several independent variables into consideration when formulating a treatment plan. This approach enables us to incorporate a comprehensive decision-making process as it relates to outcomes. This algorithm can help predict clinical outcomes of a specific patient who is a candidate for more than one possible cartilage procedure and tests the likelihood of success following each theoretical procedure allowing alterations in modifiable risk factors such as BMI, smoking and others [115, 116]. We believe that integrated human and machine learning decision-making will enable improvements in patient selection and facilitate a new era of patient-tailored or customized evidence-based clinical care (Figure 17A,B).

7 | Summary

This manuscript embodies a comprehensive collection of collaborative work that includes basic science, translational and clinical outcomes research developed and published for more than 25 years at Rush University Medical Center in Chicago. This is a team-science collaborative effort with multiple basic and clinician scientists to improve decision-making, graft availability, surgical technique and to identify the role of several independent variables that may lead to more predictable outcomes following OCA transplantation and optimized patient care.

Author Contributions

B.J.C. contributed to the initiation, conceptualization, organization, drafting, reviewing, coordinating, and supervising of this manuscript. J.A.C. contributed to the organization, drafting, and reviewing of this manuscript. S.G.C. contributed to the organization, drafting, and reviewing of this manuscript. R.M.F. contributed to the organization, drafting, and reviewing of this manuscript. R.G. contributed to the initiation, conceptualization, organization, drafting, and coordination of this manuscript. A.B.Y. contributed to the conceptualization, organizing, drafting, reviewing, and supervising this manuscript. All investigators of this submission are authors and/or co-authors for references in this manuscript.

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Conflicts of Interest

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