Utilization of Orthobiologic Augmentation for Meniscal Repairs: Current Concepts and Future Perspectives

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Abstract

Introduction

Meniscal tissue is a complex structure and performs a vital role in the normal biomechanical functioning of the knee joint. Unfortunately, Meniscal tissue lacks vascularity and therefore demonstrates poor healing potential. To improve meniscal healing biological therapies have been used to enhance meniscal repairs and improve repair outcomes. Newer therapies incorporate growth factors and mesenchymal stem cells (MSC) to improve the probability of healing and patient treatment outcomes under the term orthobiologics. These have been delivered in isolation or as an adjunct to surgery as injectables.

Objective
To give a narrative review of orthobiologics utilized in meniscal repair therapies and determine their effectiveness and role in treating meniscal tears.

Methods
A literature search was conducted using the PubMed (MEDLINE) and EMBASE databases in April 2021 without any date restrictions. Any relevant literature describing orthobiologic therapies utilized in meniscal repair was identified from the clinical databases and a narrative review was undertaken.

Results
Currently, the predominant orthobiologics used in clinical settings are autologous platelet-rich plasma (PRP) and mesenchymal stem cell-based therapies. These have indicated clinical benefits and, in a few, enhanced meniscal repair. Standardizing PRP remains challenging and is essential to consider to provide uniformity in treatment. Both therapies appear safe with no significant adverse effects, and MSC-based therapies do not show any increased risk of tumorigenicity.

Conclusion
Orthobiologics in meniscal tears have shown mild to moderate clinical benefit, as demonstrated in a small series of clinical studies. However, literature on clinical results is scarce, and pre-clinical data remains the justification for these therapies. Larger, well-designed trials will determine their true benefit, and combining them with tissue engineering techniques may improve results in the future.

Keywords: Meniscus, Orthobiologics, PRP, MSCs, Stem cell therapy, Meniscal Repair
**Introduction**

Biologic therapies have become increasingly popular over the last two decades with ever-increasing indications. A vast majority of these treatments are related to musculoskeletal orthopedics but include various other fields of medicine(1–5). Meniscal injuries are a practical dilemma faced by orthopedic surgeons globally, and treatment recommendations have evolved from the removal of torn meniscal tissue to meniscal repair and preservation(6–8). Meniscal tissue has a poor healing capacity owing to its avascularity, particularly in the central white-white zone(9,10). The meniscus is an intra-articular structure surrounded by flowing synovial fluid, which hinders clot formation and healing. In addition, the major biomechanical forces acting on the meniscus continuously displace and further damage the tissue(11).

Various implants and techniques are used in meniscal repairs, where sutures are passed within or across the tear to approximate the tissue and restore its continuity(12). Despite the technique used, meniscal repairs performed without biological augmentation demonstrate a failure rate of 20-30%(13,14). Literature has shown that meniscal repair when done alongside an anterior cruciate ligament reconstruction, had a better healing rate at long term follow up(15). Biologic therapies could reduce the high failure rate of meniscal repairs and prevent the need for revision surgery(11).

Commonly used biologics include platelet-rich plasma (PRP) and mesenchymal stem cell based therapies. These are administered locally into the affected joints during or after arthroscopy as an adjuvant to a surgical repair(16–19). Numerous pre-clinical studies have been the basis for the clinical application of these therapeutics.

**Cell-free therapy**

Clinical cell-free therapies in biologics utilize growth factors, cell products, or biomaterials which can aid in healing the injured tissues by encouraging local inflammatory and healing responses. Such therapies include PRP, hyaluronic acid (20–22) and biomimetic gels. However, in terms of meniscus tear treatment, only PRP has been popular in clinical practice; other mentioned modalities remain in pre-clinical phases.

**Platelet rich plasma**

PRP, a concentrated autologous processed blood-based product, has been employed to assist meniscal healing(23). From animal work the postulated mechanism of delivery of a high concentration of growth factors and bioactive proteins stimulates an inflammatory response in the delivered tissue promoting angiogenesis(24,25). The delivered PRP will then promote blood flow into an otherwise avascular tissue and allow for the healing of the tear. The platelets predominately mediate this as in normal physiological healing response. PRP has now commercially available from various companies with proprietary preparation systems and formulations, all with the similar goal of concentrating the blood platelet component. The quandary that has arisen is that each method of preparation results in a diverse formulation of PRP. In addition, the autologous nature of the treatment itself brings in the difficulty of standardization and the differences in preparation(26). Nonetheless, PRP has become increasingly popular for use in musculoskeletal orthopedics. Among biologics, there
Kaminski et al. reported two prospective randomized control trials (RCT) where the first study group underwent a meniscal repair with augmentation with thrombin activated leucocyte rich PRP (28,29). Among thirty-seven patients, 18 received activated PRP into a vertical meniscal tear repaired using an all-inside or outside-in repair. The activator was a combination of 20mM CaCl$_2$ and 25IU/mL of autologous thrombin. The control group received 0.9% saline instead. Second look arthroscopy and MRI at 18 weeks demonstrated 85% successful healing in the PRP augmented group versus 47% in the control group, which was statistically significant. Patient-reported outcomes were also significantly higher in the PRP-treated group except for the visual analogue score. They concluded that PRP augmentation was beneficial in promoting the healing of vertical meniscal tears with no adverse effects (28). In the second study, the intervention group underwent meniscal trephination with PRP augmentation. Here in chronic meniscal tears underwent percutaneous trephination and a delivery of thrombin-activated PRP under ultrasound guidance against a control group that only received trephination. MR arthrography was performed at 33 weeks and demonstrated improved healing rates in the PRP group however, the difference was not significant. Patients with failure to heal underwent a partial meniscectomy. When the cumulative failure rate was considered PRP augmented patients had a significantly improved outcome and reduced the risk of a second arthroscopy (8% vs. 28%). Pain and functional patient-reported outcome scores significantly improved in both groups (29). Both studies did not report significant complications and deemed the treatments safe.

A systematic review by Sochacki et al. (30) reported a comparative study where PRP was added to an arthroscopic meniscal repair. Their review included five articles that demonstrated a lower failure rate in repairs with the addition of PRP of 4.4% to 26.7%, while without PRP, 13.3% to 50% failure. Of the five articles, one used a PRP fibrin, while the remainder used leucocyte-rich PRP. Only one of the five studies reported improved patient-reported outcomes and better function. Though the addition of PRP improved failure rates, patient outcomes were not significantly better in most of the included studies.

Belk et al. (27) reviewed six studies reporting on the results of meniscal repair with and without PRP. Five of the six studies reported the use of leucocyte-rich PRP while one did not report the formulation of PRP used. Two included studies were level I, while 4 were level III. With a mean follow-up of 32.8 months, they, too, noted a slightly lower failure rate in the PRP-treated group compared to the non-PRP group (17% vs. 22.1%). Only two studies reported significantly better outcome scores. They concluded that the addition of PRP did not improve midterm outcomes significantly compared to conventional meniscal repair. However, this conclusion is drawn using limited data and a lack of high-quality studies. It is worth noting that the review by Belk et al. (27) and Sochacki et al. (30) did share four papers again indicating the scarcity of literature on the subject.

A large cohort study including 550 subjects studied the benefit of performing a meniscal repair with or without PRP augmentation and whether in the setting of or not an ACL reconstruction (31). They found PRP meniscal repair augmentation to be mildly effective in reducing failure rates, where the PRP group had a failure rate of 14.6% and the non-PRP 17%. However, they also noted that in the setting of an ACL reconstruction, there was no significant difference in failure. Probably due to the increased bleeding and growth...
factor concentration within the knee joint as a result of bone tunnel drilling during ACL reconstruction.

In a cohort study in 2015(32) PRP was adjunct to an open meniscus repair. The study included 34 patients with a mean age of 28 years who underwent an open meniscal repair for a horizontal tear extending to the avascular zone. Seventeen patients of 34 received the additional PRP at the repair site. MRI scans at 1-year follow-up demonstrated complete healing in 5 patients in the PRP group and none in the non-PRP group. The mean KOOS score was significantly improved in the PRP group versus the non-PRP group, as while the mean IKDC scores were higher in the PRP group (87.9 to 90.7), this did not reach statistical significance. In addition, failure rates were better in the PRP group (5.8% vs. 11.8%), and the addition of PRP was possibly improved meniscal substance healing.

Genoun et al.(33) studied the effect of a percutaneous ultrasound-guided intrameniscal PRP injection delivered to degenerative tears in 10 subjects. 0.5 ml of PRP was delivered along with local anaesthesia into the tear site, 1.5ml into the meniscal wall, and 2 ml into the peri-meniscal space. Patients were followed up at 3 and 6 months and assessed using KOOS, VAS, and return to sport, along with a post-injection MRI at six months. They noted significant improvement in KOOS (56.6 to 72.7) and an improved VAS score (57 to 33) which was not statistically significant. Post-injection MRI scans also showed stable healed tears. Percutaneous delivery of PRP has the additional advantage of being minimally invasive. However, due to the small sample size and lack of a control group, the study’s conclusion is guarded. Another similarly designed study reported on 15 patients and evaluated them with Lysholm scoring and MRI at a mean of 32 months(34). They reported significant improvement in clinical scoring and regression of meniscal degeneration.

Yang et al.(35) included 61 patients in a study with a meniscal injury who underwent all inside or outside in meniscal repairs. Thirty-one subjects received no PRP, and thirty received three consecutive doses of percutaneous knee PRP injections in the outpatient at 2,4, and 6 weeks post-operatively. Their rationale for this was that repeated doses would increase vascularity and reduce the chance of non-healing. In addition, PRP would not be pushed out or diluted by saline used in the arthroscopic surgery. The study followed up on the patients for 24 months and found no significant difference in outcome scores. Mean IKDC was 72 in the non-PRP group and 75 in the PRP group. Mean Lysholm scores were 80 in the PRP group and 77 in the non-PRP group. They also had similar healing rates of 93.3% in the PRP group and 87.1% in the non-PRP group. The authors concluded that PRP did not provide significant benefit compared to an isolated meniscal repair. They did however, have a significant selection bias and lack of control in the study. This study is the only study to administer repeated PRP doses that revealed no significant clinical benefit.

The present PRP data for meniscal repairs is scarce, and even most systematic reviews compile level III data and cannot make explicit recommendations for its use(26). It does seem to be a safe therapy. However, concerns about preparation standardization and activation methods remain a significant issue resulting in variations in the make-up of PRP (26,36). Along with this, the autologous nature of the treatment relies on the individuals' baseline blood values, which raises concerns about uniformity. DeLong proposed the PAW classification system to categorise PRP preparations to help compare literature and the variations in composition and manufacturing techniques. The classification considers the platelet count, the platelet activation method, and the total leucocyte count. Classifying each study based on the simple PAW system allows for better determination of the PRP methods.
and contents used in each trial (37). From the articles mentioned in our review, we noted that most studies utilized leucocyte-rich PRP with thrombin activation. Table 1 summarises the PAW classification system.

<table>
<thead>
<tr>
<th>Author/ Year</th>
<th>Study Level of Evidence</th>
<th>Participants</th>
<th>Age (yrs)</th>
<th>Outcome</th>
<th>Tear Morphology/ Intervention</th>
<th>Follow up (months)</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kaminski et al (28)/2018</td>
<td>Prospective RCT/I</td>
<td>37</td>
<td>PRP:36</td>
<td>Second look arthroscopy, MRL, VAS, IKDC, WOMAC, KOOS</td>
<td>Unstable complete vertical longitudinal tear/ All inside repair with activated CaCl2 PRP + Thrombin</td>
<td>54</td>
<td>At 18 weeks PRP group demonstrated significantly better healing. Significant improvement in IKDC, WOMAC &amp; KOOS scores. No significant difference in VAS scores.</td>
</tr>
<tr>
<td>Kaminski et al (29)/2019</td>
<td>Prospective RCT/I</td>
<td>72</td>
<td>PRP:44</td>
<td>VAS, IKDC, WOMAC, KOOS</td>
<td>Chronic tears/ Prepatellar Meniscal repletion + PRP with thrombin</td>
<td>23</td>
<td>Significant improvement in VAS &amp; KOOS scores exceeding MCID value in majority of patients. MR Arthrography showed superior healing in the PRP group. Treatment success was higher in PRP group with less numbers of revision surgery with meniscectomy.</td>
</tr>
<tr>
<td>Sochacki et al (30)/2020</td>
<td>Systematic Review/III</td>
<td>274</td>
<td>PRP:110</td>
<td>IKDC, WOMAC, Lysholm scale, VAS, Tegner Activity, KOOS</td>
<td>All types/ Meniscal repair +PRP</td>
<td>29.2</td>
<td>Meniscal repairs without PRP has a lower failure rate. One study reported higher WOMAC and KOOS score.</td>
</tr>
<tr>
<td>Belk et al (27)/2020</td>
<td>Systematic Review/III</td>
<td>754</td>
<td>PRP:31.9</td>
<td>VAS, IKDC, WOMAC, KOOS, Lysholm score</td>
<td>All tear types/ Inside our repair + PRP</td>
<td>32.8</td>
<td>17% failure in PRP group vs 22.1% in non PRP group. One study reported sig improvement in IKDC, another in WOMAC and another in KOOS in the PRP groups.</td>
</tr>
<tr>
<td>Everhart et al (31)/2019</td>
<td>Cohort study/III</td>
<td>550</td>
<td>PRP:30</td>
<td>Failure defined as revision surgery, non-healed tears on second look, meniscectomy</td>
<td>All types + ACL tear/ Inside out, all inside, root repair +/- ACL Recon</td>
<td>36</td>
<td>Higher Meniscal failure rate in patients without PRP 17% vs 14.6%. In the presence of ACL recon PRP did not reduce the risk of failure.</td>
</tr>
<tr>
<td>Pujol et al (32)/2015</td>
<td>Cohort study/III</td>
<td>34</td>
<td>PRP:32.3</td>
<td>KOOS, IKDC, MRI</td>
<td>Horizontal cleavage tear/ Open repair + PRP infiltration</td>
<td>32.2</td>
<td>PRP group had significantly better KOOS scores, 5 cases in PRP group showed complete disappearance of tear on MRI and none in non PRP group.</td>
</tr>
<tr>
<td>Genoun et al (33)/2019</td>
<td>Case control/IV</td>
<td>10</td>
<td>KOOS, VAS, MRI</td>
<td>Degenerative tears/ USG guided Intrameniscal PRP injection</td>
<td>6</td>
<td>Significant improvement in KOOS scores from 56.6 to 72.7. Post op MRI showed stability of tears but no healing with no onset or progression of OA.</td>
<td></td>
</tr>
<tr>
<td>Ozylvac et al (34)/2018</td>
<td>Case control/IV</td>
<td>15</td>
<td>Lysholm score, MRI</td>
<td>All types/ USG guided PRP</td>
<td>31.9</td>
<td>Statistical improvement in Lysholm score, 4 patients had improved radiological scoring on MRI.</td>
<td></td>
</tr>
<tr>
<td>Yang et al (35)/2021</td>
<td>Cohort study/III</td>
<td>61</td>
<td>PRP:30</td>
<td>IKDC, Lysholm Failure defined as revision surgery</td>
<td>All types/ all inside or inside out repair + 3 PRP injection at 2,4,6 weeks post</td>
<td>24</td>
<td>Similar improvement and failure rates in both groups.</td>
</tr>
</tbody>
</table>
Cell based Therapies

Cellular therapies have become increasingly popular in the last 30 years, and a significant amount of clinical work has involved chondral regeneration(38,39), especially concerning autologous chondrocyte implantation(40). Stem cells, in particular, have been an exciting avenue for regenerating tissues, with a great deal of translational work showing immense potential. Most musculoskeletal cells are generated using MSCs in pre-clinical research. However, owing to the complex phenotype and functional demand of meniscal tissue, meniscus tissue is challenging to regenerate(11). The use of tissue engineering has furthered research in generating neo meniscal tissue. Presently scaffolds and biomaterials have been utilized with the hope of gradual material degradation, cell recruitment, and ultimately regeneration(41,42). MSCs can augment meniscal tears via delivery into the tear site via arthroscopic portals. From pre-clinical papers, MSCs seem to be a practical, workable solution; however, clinical studies remain scarce(43–46).

MSC Augmentation

Few studies have used MSC augmentation in meniscal repairs and have limited sample sizes. In a case report by James et al.(47), one patient underwent a criss-cross meniscal repair alongside delivery of a mixture of autogenous bone marrow aspirate concentrate (BMAC) and PRP. The authors noted complete healing on second look arthroscopy at six months postoperative, and at 12 months, the patient was at a pre-injury activity level. In this study, despite employing undifferentiated MSCs in the form of BMAC, the authors were cautious about reporting the success of the repair to be attributed entirely to the biologic preparation. They did conclude it was indeterminable with this one study.

In a case series by Sekiya et al. six patients underwent meniscal repair, where four patients had flap tears and 2 with radial tears(18). Here the meniscal tear was repaired alongside arthroscopic transplantation of autologous synovial derived MSCs two weeks after the repair. During the meniscal repair arthroscopy, synovial tissue was harvested and then underwent culture expansion in vitro. In a second dry arthroscopy two weeks later, the cells were transplanted into the repair site. The authors objectively reported the outcomes using MRI and second-look arthroscopy showed significantly improved healing where the tears were completely healed in 4 patients and partially in 2. Synovium is an excellent source of MSCs, with the only problem being that the tissue requires significant expansion in vitro(48). However, the two-stage therapy is beneficial as the cells can be standardized and

characterized prior to implantation. It is important to note that cell-based therapies in most countries are highly regulated, and only the FDA permits minimally manipulated therapies. The result is that the cellular numbers used in these therapies are deficient compared to the number achieved in the study mentioned above.

There is a paucity of clinical literature utilizing MSCs to augment meniscal tears biologically, and with the few publications, the sample sizes remain very small. Despite encouraging objective results in pre-clinical literature, the clinical scenario for using MSCs for meniscal treatments remains relatively undetermined.

<table>
<thead>
<tr>
<th>Author/Year</th>
<th>Study Design/Level of Evidence</th>
<th>Participants</th>
<th>Cell Source/Number/Intervention</th>
<th>Outcome</th>
<th>Follow Up (Months)</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>James et al(47)/2014</td>
<td>Case Report/V</td>
<td>1</td>
<td>Autogenous BMAC + PRP/ Meniscal repair and arthroscopic delivery</td>
<td>MRI and Second look Arthroscopy</td>
<td>12</td>
<td>Complete tear healing at 6 months and 1 year post-operative patient was asymptomatic and back to sports.</td>
</tr>
<tr>
<td>Sekiya et al(18)/2021</td>
<td>Case Series/IV</td>
<td>6</td>
<td>Autogenous SynMSCs, (4x10⁷), Meniscal Repair and Arthroscopic SynMSCs Delivery</td>
<td>Second look Arthroscopy, MRI, Lysholm Knee Score</td>
<td>13</td>
<td>Significantly improved Lysholm score, Significantly improved healing to stable smooth tissue in central zone of tears of 2 patients and partially in 2 for flap tears. Radial tears complete healing</td>
</tr>
</tbody>
</table>

**Scaffold Cell Therapy**

Recently, newer techniques in stem cell biologic augmentation have been explored for both cartilage and meniscus regeneration. Synovium has recently been preferred over the previously used bone marrow and adipose MSCs as they have demonstrated superior proliferation and differentiation potential(48,49). In addition, cellular therapies have been combined with biomaterials and other biomimetic constructs that aid in cellular growth and regeneration. Such techniques include 3D printing and nanotechnologies, which help fabricate biomaterials to resemble porous tissues, which will potentiuate cytotherapies(50–52).

Whitehouse et al.(19) injected autologous Bone Marrow MSCS into a collagen scaffold and incorporated this into a meniscal repair using vertical mattress sutures in five patients. Three of the five patients reported clinical improvement and no evidence of meniscal tear on repeat MRI at six months. However, two patients continued to be symptomatic with failure to heal on MRI and underwent a subsequent meniscectomy at 15 months. They concluded there were no adverse effects and that the treatment showed promise despite two in five having treatment failure. However, using a scaffold to provide a
microenvironment for the cells could potentiate their growth and differentiation, and further studies with larger sample sizes are required.

<table>
<thead>
<tr>
<th>Author/Year</th>
<th>Study Design/Level of Evidence</th>
<th>Participants</th>
<th>Cell Source/Number/Intervention</th>
<th>Outcome</th>
<th>Follow Up (Months)</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whitehouse et al. (19)/2017</td>
<td>Case Series/IV</td>
<td>5</td>
<td>Autogenous BM derived MSC with collagen scaffold and meniscal repair</td>
<td>MRI, Tegner-Lysholm score</td>
<td>24</td>
<td>3 patients had clinical improvement at 12 months and no evidence of tear on MRI at 24 months. 2 patients underwent meniscectomy due to failure to heal</td>
</tr>
</tbody>
</table>

**Future Perspective**

Newer cell therapies using better cell sources and culture methods are being researched with the intent of better clinical outcomes. One such treatment by Ando et al. (53,54) developed a three-dimensional scaffold-free therapy known as a tissue-engineered construct (TEC). TEC consists of a high-density monolayer culture of synovial-derived MSCs which results in a three-dimensional suspension of cells that can then be implanted anywhere in the body. TEC has been reported in a first-in-human clinical trial of 5 subjects for use in chondral defects and has shown excellent results (55). Objective outcomes using MRI, second look arthroscopy, and tissue biopsy, which showed excellent defect fill with hyaline cartilage. With the favourable evidence from these studies, the authors are currently performing a larger randomised control clinical trial for which patient recruitment is completed. With promising results of TEC in chondral regeneration, the same group has been investigating the potential use of TEC in meniscus repair and regeneration. Such studies are in the pre-clinical phase using a porcine meniscus model (56). TEC was used to fill a cylindrical defect artificially made in the meniscus body. At six months, all the menisci treated with TEC showed excellent healing with fibrocartilaginous tissue with good tissue integration. TEC was then combined with an electrospun scaffold in a rabbit model (57). Here, the rabbit joints treated with the scaffold and TEC demonstrated a chondroprotective effect on the joint's articular surfaces in addition to less meniscal extrusion and concluded that this combination could emulate and manage meniscal hoop stresses as a native meniscus would. They concluded that it was important to emulate the radial collagen fibre arrangement on the meniscus tissue to enhance the repair and the electrospun scaffold could achieve this. Shimomura et al. noted this in a rabbit model where meniscal radial tears were repaired by wrapping the tear site with TEC and a nanofibrous scaffold (58). There is a basis for clinical trials investigating TEC and tissue engineering for meniscal healing. TEC could be delivered to a tear site as an adjunct to meniscal repair via an injectable method. Cellular therapies would contribute to the biological component of a repair while scaffolding and fibre
arrangement using tissue engineering would address the functional demand, favourable microenvironment and provide a mechanical advantage.

Due to the mechanical function of the meniscus, treatments have aimed at functional repair of the meniscus by using a bioactive biomaterial, adding an element of mechanical integrity to the repair and a microenvironment for the cells to populate and regenerate the meniscal tissue. More recently, a team from Stanford has developed a biomimetic gel known as HYALEX®(Lexington, MA) Cartilage which has proven to be effective in rabbit models HYALEX®(Lexington, MA) consists of two polymers that provide strength and lubricative properties to the construct(59). Such gels and biomaterials could be helpful in meniscal regeneration in the future, and we may see off-the-shelf treatment options becoming available.

**Conclusion**

Biologic augmentation of meniscal tears has immense potential in the treatment of meniscal tears, especially in clinical scenarios where traditional repairs have unacceptably high failure rates. Delivery of a physiological, biologically active therapy would emulate and encourage the body's innate healing response. At present biologic augmentation has not had predictable outcomes, and to date, literature has only been able to deem it a safe therapy when used autologously. Biologic augmentation for meniscus repair in the future must aim for standardization of treatment with large, rigorously designed trials to determine their effectiveness. Pre-clinical data will lead the way forward for bedside utilization of such modalities.

**Declaration of competing interest**

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.
Bibliography


Table. 1 Summarises the PAW classification table and how each preparatory method of PRP can be classified.