

## American Association of Hip and Knee Surgeons Position Statement on Biologics for Advanced Hip and Knee Arthritis

An increasing number of facilities and physicians have begun to offer intraarticular injections of stem cells and platelet rich plasma (PRP) as a therapeutic intervention to patients with advanced hip and knee arthritis. These injections are often marketed directly to the public based on the promise of pain relief and healing of damaged cartilage. Improvements in joint function, reduction in pain, and an increase in cartilage in the affected joint are often touted as potential benefits. Patient testimonials or expert opinions are often used to demonstrate that these "natural" alternatives to major surgery are effective. However, these claims are not based on scientific evidence. Furthermore, these treatments have not been standardized, are often administered without approval from the Food and Drug Administration (FDA), and are typically very costly to the patient as they are not covered by insurance companies. In the absence of regulatory oversight, the formulations for the biologic injections may vary dramatically between manufacturers, preparation, processing, host biology, anatomic location, and disease type.

Biologic treatments such as stem cell and PRP injections have some promising applications in many different areas of health and medical research. There is potential for these treatments to repair damaged tissues and augment the body's reparative process following injury. With regard to orthopaedics, stem cells may have the potential of regenerating damaged cells and developing into bone and cartilage. PRP contains growth factors that may reduce inflammation and promote healing. Unfortunately, highly preliminary basic science research has prematurely led to the rapid promotion of these technologies for clinical use in a number of diseases including osteoarthritis.

Osteoarthritis is a slowly progressive degenerative disorder that involves damage to joint cartilage, structural changes in bone, and inflammation of the soft tissues around the joint. Advanced arthritis involves complete loss of cartilage and exposure of damaged bone (so-called "bone-on-bone arthritis"). Unfortunately, there is currently no curative treatment for advanced hip and knee arthritis. For many patients with advanced hip and knee arthritis, nonsurgical management results in continued pain and loss of function that negatively impacts quality of life. Total hip and knee arthroplasty is evidence-based and remains the mainstay of treatments for those with advanced degenerative disease who fail nonsurgical management. While joint replacement has been shown to be very effective at improving quality of life for most patients, surgery is not without risks and associated fears for some patients.

The published literature studying the use of biologics for the treatment of osteoarthritis is evolving. Some evidence suggests that PRP may temporarily improve the symptoms of mild to moderate osteoarthritis of the knee. However, there is little data to suggest it will benefit patients with advanced osteoarthritis. Furthermore, there is no data to support the idea that stem cells can sense the environment into which they are injected and repair damaged tissue. The claim that either PRP or stem cells regenerate severely damaged or lost cartilage is not supported by scientific evidence. The limited amount of available scientific evidence is troubling and does not allow an assessment as to whether the potential clinical benefits of such therapies outweigh any potential harms, or if these biologic therapies are more cost-effective than standard treatments such as acetaminophen, oral anti-inflammatory agents or corticosteroid injections.

While the efficacy of these treatments has yet to be established, the potential for harm clearly exists and is likely underappreciated. While PRP is generally considered safe, the injection of any substance in the knee carries the potential for complications including intraarticular infection. Multiple cases of serious harm have been documented following stem cell treatments, and these adverse events are likely underreported given the current regulatory environment. It is paramount that the safety of these treatments be fully established before they can be supported for routine use.

It is therefore our position that biologic therapies, including stem cell and PRP injections, cannot currently be recommended for the treatment of advanced hip or knee arthritis. With unproven benefits, high out-of-pocket costs for patients, and clear safety concerns, we do not support the routine clinical use of these therapies. While we do recognize the potential benefit of biologic therapies, we encourage rigorous, well-designed clinical trials to establish the safety, efficacy, and cost-effectiveness of these potential treatments prior to widespread adoption.

## This statement has been endorsed by:

The Hip Society The Knee Society

This statement is an expression of the policy of the American Association of Hip & Knee Surgeons. It is not a comprehensive review of the subject nor is it intended as medical advice for the treatment of individual patients.

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