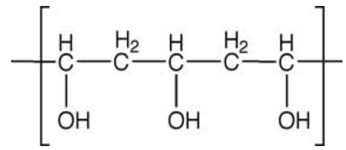
CARTIVA™
Synthetic Cartilage Implant

TECHNICAL BULLETIN

#CTV-01 Rev. A

Polyvinyl Alcohol for Medical Applications

Polyvinyl alcohol (PVA) is a linear synthetic polymer prepared by the hydrolysis of the parent polymer polyvinyl acetate, resulting in a mixture of 10-50% polyvinyl acetate in water or saline. Depending on the degree of polymerization and hydrolysis of the precursor polymer, the physical properties of PVA can be customized to defined functional requirements. PVA is highly soluble in water but resistant to most organic solvents, resulting in broad applications in the medical and pharmaceutical industries.



For the majority of pharmaceutical uses, the non-toxic and water-soluble properties are useful for tablet binders and coatings. However, the properties of PVA can be further modified by crosslinking, a process whereby individual polymer chains are connected to yield a tough and physically stable matrix. Chemical or physical crosslinking of PVA produces a material that is inert, viscoelastic and lubricious – attractive properties for medical device applications. Chemical crosslinking utilizes an added multi-functional molecule to chemically bond together the PVA polymer chains, while physical crosslinking employs localized crystallization of the PVA molecules to create physical linkages between multiple polymer chains. A crosslinked PVA matrix is no longer water soluble, but can be swollen to produce a hydrogel, a gel where the swelling agent or sol phase is water. Typical device applications utilize hydrogel-forming properties of PVA.

PVA has been successfully used in medical device applications for over 20 years. Extensive biocompatibility and functional performance testing have demonstrated the suitability of stabilized forms of PVA for critical patient contact uses including permanent implant and blood contact applications. The resulting devices exploit the unique combination of strength, swellability, lubricity, and flexibility of the hydrogel materials. These applications include contact lenses, ocular wetting solutions, vascular embolic agents, hydrophilic coatings, tissue adhesion barriers and nerve guides.

Hydrogels for Cartilage Replacement

With the widespread acceptance of hydrogels as biomaterials, came the consideration for their use as a replacement for damaged cartilage. Cartilage, typically comprised of 60-80% water with a mass balance primarily of collagen, is the prototypical biologic hydrogel. The physical properties of several synthetic and hybrid synthetic/biologic hydrogels (such as Cartiva™ Synthetic Cartilage Implant (SCI)), in terms of water content, compressive properties, fatigue resistance and lubricity, make them excellent candidates for direct replacement of damaged articular cartilage (Table 1). In fact, physically crosslinked PVA hydrogels prepared via freeze/thaw cycling, or cryogels, were the first PVA materials to be successfully used for articular cartilage resurfacing in the late 1990's.

TABLE 1	Articular Cartilage	Cartiva™ SCI*	Comment
Water Content	60 – 80%	60%	Equilibrium water content is similar to native cartilage. At the lower range of cartilage, Cartiva will not be dehydrated.
Compressive Modulus	0.5 to 1.0 MPa	2.5 – 3.0 MPa	Marginally stiffer, Cartiva supports compressive loads but provides cushioning. Moduli of other replacements are typically > 100 GPa.
Coefficient of Friction	<0.01 – 0.05	0.04 – 0.07	Cartiva against porcine cartilage shows lubricity similar to normal cartilage against cartilage.

PVA cryogels used in cartilage resurfacing are prepared from high molecular weight, highly saponified polymers in relatively high concentrations (≥ 30% PVA). These cyrogels have water contents similar to surrounding healthy cartilage and are osmotically balanced with the fluids and tissues within the joint. Stringent control of the PVA composition and the freeze/thaw process is used to prepare cryogels with compressive properties (aggregate modulus and creep) and wear resistance similar to native cartilage.[1] In addition, PVA cryogels exhibit biphasic mechanical properties with rapid water loss under initial compression similar to normal articular cartilage, as well as a low coefficient of friction due to fluid-film formation upon loading.[2]

Due to the similar properties of PVA cryogels to native cartilage, joint resurfacing with these materials does not require replacement of the opposing articular surface. The PVA device articulates against cartilage with no apparent damage. Consequently, joint resurfacing with these devices is faster, does not require significant removal of healthy tissue or its replacement with a durable bearing surface, and thus typically results in less surgical trauma and faster recovery times.[3]

Clinical experience with the use of PVA cryogel devices for cartilage repair has been generally positive. Since 2002, several thousand devices have been implanted in a variety of joints including the metatarsophalangeal joint, knee, shoulder and talus. Although there have been no randomized clinical trials to date, the initial experience suggests that PVA cryogels provide restoration of the joint surface with the desired relief of pain and return to function when implanted in appropriately selected patients with good surgical technique.[3,4]

References

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2. Murakami T, et al. Adaptive multimode lubrication in natural synovial joints and artificial joints, Proc Inst Mech Eng H. 1998;212(1):23-35.
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4. Maiotti M, et al. The Use of Poli-Hydrogel Cylindrical Implants to Treat Deep Chondral Defects of the Knee. Presented at: Arthroscopy Assoc.of N Amer, Vancouver, BC; 2005.

*Cartiva SCI is not approved for sale in the US.