ArCom®
PROCESSED POLYETHYLENE

Resin and Consolidation Issues with UHMWPE

BIOMET® INC

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Ultra high molecular weight polyethylene (UHMWPE) wear continues to be a major issue in orthopaedics today. Numerous articles are being published on polyethylene, and the orthopaedic community is becoming more aware of the issues relating to polyethylene wear.

Many factors which affect polyethylene performance have emerged. Two major factors which can influence polyethylene wear resistance are starting resins and degree of consolidation.

Biomet has taken a very proactive stance in addressing polyethylene performance issues. An example is ArCom,® argon packaged, compression molded polyethylene, which was developed with a focus on reducing polyethylene wear. Biomet continues to assess polyethylene performance and to adapt appropriate, proven technology to provide solid solutions to today's most important wear problems.

Polyethylene Resin:

The base resins used to make polyethylene contain variable amounts of catalyst and trace elements. The process, which involves converting the ethylene gas into powder resin, is conducted by one of the two resin manufacturers in the United States. Hoechst-Celanese and Montell are the two domestic companies who supply raw resin used to manufacture orthopaedic bearing material.

Common trace elements found in the resin are aluminum, titanium, calcium and chlorine. ASTM and ISO have set guidelines for allowable amounts of trace elements remaining in the polymer resin. The catalysts used during the conversion process are not disclosed by the manufacturers, and trace elements may result from the catalysts used to convert the gas to resin.

UHMWPE grades vary depending on additional additives blended with the powder, intrinsic viscosity, trace elements, particle size and particle morphology. Calcium stearate (a common additive) is added to the resin to act as a chlorine scavenger, corrosion inhibitor and a flow agent to aid in processing.

Converters do not commonly process resin with a low stearate content because it can corrode processing equipment and can be more difficult to extrude. Therefore, extruders typically process stearated resins despite the fact that stearates have been shown to cause voids and affect consolidation in the finished extruded bar products.[1,2,3]

The most commonly used resin grade for extruded bar UHMWPE in the United States is GUR 4150HP from Hoechst. The GUR series of UHMWPE resins includes 402, 405, 412 and 415 GURs. Within this series, the lower number indicates a lower molecular weight. Hoechst Germany manufactures the "1000 series" of resins which include 1020, 1050, 1120 and 1150. Resins from Montell used for UHMWPE for production of orthopaedic bearings are 1900, 1900L, 1900H and 1900CM.

One method for differentiating resin grades is by conducting intrinsic viscosity (I.V.) testing (ASTM D 4020). This test is also a reflection on molecular weight. Higher molecular weight resin is related to greater abrasive wear resistance.[3,4,5] Intrinsic viscosity testing is done by dissolving the resin in a heated solvent and then measuring the viscosity of the mixture.

Figure 1 shows the manufacturer, stearate additives and molecular weight ranges for various resins.

Resin	Manufacturer	Stearate	Approximate Molecular Weight
4150HP	Hoechst-Celanese	Yes	5 Million
415	Hoechst-Celanese	Yes	5 Million
412	Hoechst-Celanese	Yes	3.3 Million
405	Hoechst-Celanese	No	5 Million
402	Hoechst-Celanese	No	3.3 Million
1150	Hoechst Germany	Yes	5 Million
1050	Hoechst Germany	No	5 Million
1120	Hoechst Germany	Yes	3.3 Million
1020	Hoechst Germany	No	3.3 Million
Hifax 1900L	Montell, USA	No	3.2 Million
Hifax 1900	Montell, USA	No	4 Million
Hifax 1900H	Montell, USA	No	5 Million
Hifax 1900CM	Montell, USA	Yes	4 Million

Figure 1. Chart of UHMWPE Resins, Manufacturer, Stearate Additives and Molecular Weight Ranges of UHMWPE Resins.[5,6]

The significance of using different resins for UHMWPE is that final material quality of a component is partially related to the base resin used for processing.[7,8] Resin is typically selected based on molecular weight (intrinsic viscosity), trace element levels, particle size distribution and cleanliness. The end users (the orthopaedic manufacturer) have little say, if any, on the resins used for the extruded bar product they purchase.

Because Biomet manufactures its own bar stock and finished polyethylene components, the resin selection process is very controlled. Typically, several non-stearated raw resin lot samples in small quantities are supplied by the resin manufacturers to Biomet. Any sample of resin which meets the in-house standards, is then processed into bar stock via isostatic molding. Testing is done to ensure that final product will provide acceptable wear resistance. Sample lots are commonly rejected and the process repeated until an acceptable lot of resin is found. Once a lot has passed inspection, processing and testing, the complete lot of resin, approximately ten to twenty tons or more of resin, is purchased.

Polyethylene Consolidation:

The wear resistance of polyethylene is not only dependent on resin quality, but more importantly, is a factor of material consolidation.[3,9,10,11] There are multiple methods to consolidate polyethylene which include ram extrusion and compression molding. The majority of components on the market today are made from ram extruded bar stock material. Other components are either direct compression molded from a resin into a finished product, or material is molded into sheets or blocks and machined into implant shapes. In addition to the common techniques, isostatic molding has recently emerged as another cost-effective manufacturing option that may offer some benefits in improved mechanical and wear properties due to improved particle fusion. All conversion processes rely on heat, time and pressure to be applied to the entire volume of resin being formed.

Each of the previously mentioned processes has advantages and disadvantages, but the key to the manufacturing of orthopaedic devices is to determine which process yields consistent and favorable mechanical properties. Differences in manufacturing between extrusion and molding may result in better consolidation in molded material.[8,10,11]

Figure 2 shows a cross-section of components taken from a hospital shelf with varying consolidation.

The reason for the varying degrees of consolidation may stem from the variance in pressure and heat during the processing of the UHMWPE resin.

Ram Extrusion:

Ram extrusion is a continuous process that produces UHMWPE bar stock of varying cross-section. The most widely used cross-sections in orthopaedic bearing manufacturing are round and rectangular. A schematic of a ram extruder is shown in Figure 3. The ram extruder operates by forcing resin into a heated die that is several feet long and has the same cross-section as that of the rod to be formed. Resin is fed from a hopper into a chamber where an oscillating ram forces the material into the die. As the powder is moved through the open-ended die, heat is applied causing the resin to expand and thereby producing resistance to the ram.

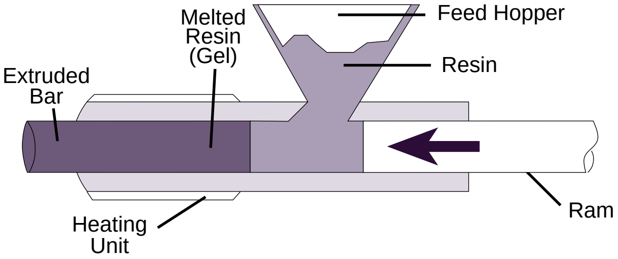
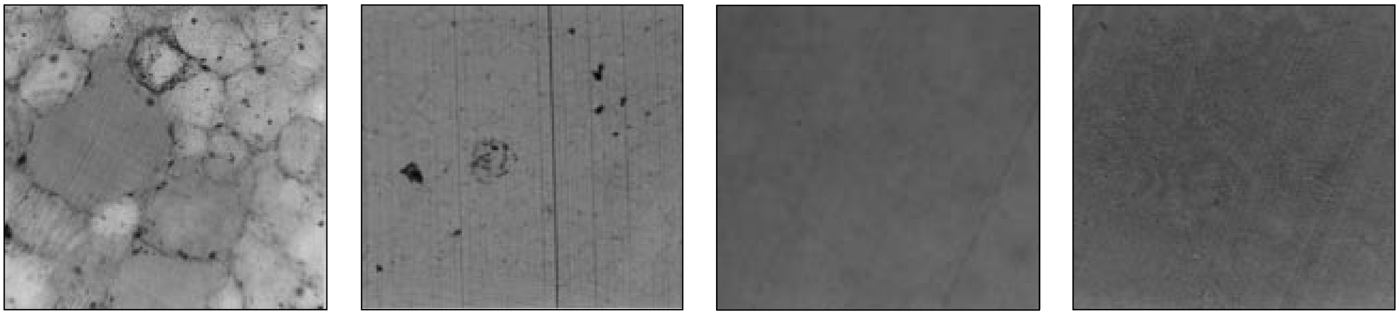


Figure 3. Extruded Bar Processing.

The resin melts from the surface to the center of the die forming a cone of unmelted material that extends into the die (Figure 4). Non-consolidated regions can result in the center of the material if the cone of unmelted material extends beyond the heated zone of the die, or if pressure is reduced prior to the cooling of the center of the extruded material (Figure 5).



100x Magnification—Cross-section of a pressure crystallized extruded bar component showing extraneous inclusions and non-consolidated areas.

100x Magnification—Cross-section of an extruded bar component showing non-consolidated areas.

100x Magnification—Cross-section of an ArCom isostatic uniform molded acetabular liner showing highly consolidated material.

100x Magnification—Cross-section of an ArCom direct molded tibial bearing showing consolidated material.

Figure 2. Consolidation of Polyethylene.[5]

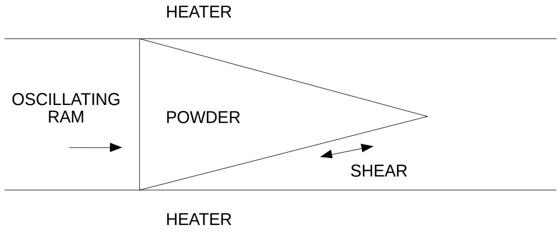


Figure 4. Unmelted Resin Cone in Ram Extrusion.

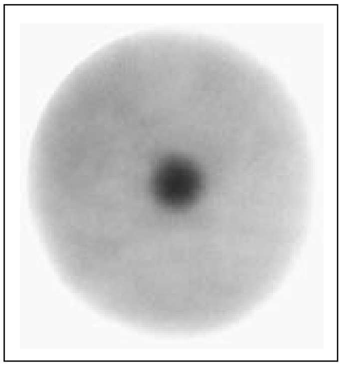


Figure 5. Non-consolidated Center in Ram Extruded Material.

In the ram extruder, pressure is applied to the melted resin by the friction of the resin against the die which resists the force being applied by the ram. It is important to note that the applied pressure is not constant but varies. These variations are due to the oscillation of the ram (on/off pressure) as well as the differences between dynamic and sliding friction as the bar is extruded, and may result in variation in the end product.

The major advantages of ram extrusion are derived from reduced cost of manufacturing, as well as volume of output. Also, the capital expenditure required for a ram extruder is much less than that required for a press to make sheet stock. The cost advantage of ram extruded material is also realized by the orthopaedic device manufacturer by the volume of output from machining devices versus molding bearings one at a time. Ram extruded material can be used to manufacture components that have tight tolerances (± 0.005 to 0.001) because it is typically purchased in the annealed form to improve dimensional stability from a converter. The cross-sectional shape of extruded material can also be tailored to meet the end use of the product.

Disadvantages of ram extrusion are the variability in pressure and heat can cause defects in the material. Stearate inclusions may also affect consolidation. A major disadvantage of ram extrusion is the variable degree of consolidation which results in inconsistent properties within the material. In addition to these inconsistencies, the annealing of the ram extruded bar for dimensional stability may also degrade the material.

Sheet Compression Molding:

Sheet molding is a form of compression molding used to manufacture large plates of material. Sheet molding utilizes large presses with multiple daylight openings. The platens on these presses often exceed thirty square feet. To form these sheets, resin is poured onto the platen and leveled with a strike bar so that a uniform resin height is maintained. Once the presses are loaded with resin, the platens are brought together and heat is applied. Some fabricators may also incorporate a bump cycle to remove any trapped gases. After a specified heating cycle has been completed, the pressure is increased to the desired set point and the material is allowed to cool under pressure. An exploded view of sheet molding platens are shown in Figure 6.

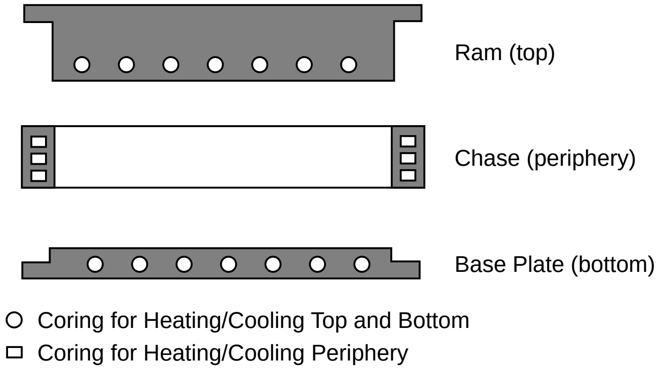


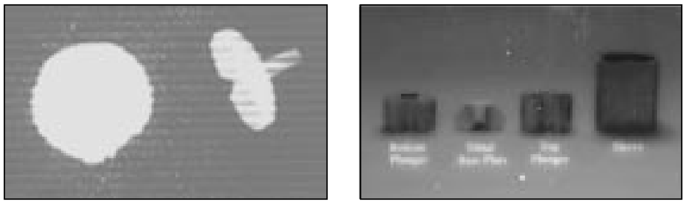
Figure 6. Sheet Molding.

The sheet formed can be of varied thickness based upon the quantity of resin loaded between the platens. The sheet that is removed from the press is usually trimmed to remove the surface that may be discolored, annealed, and then sent to the end user where the final shapes are machined from the block.

An advantage of sheet molding is that the process allows for greater pressures to be applied during the final consolidation phase compared to ram extrusion. This may result in a more uniform product than ram extrusion. One disadvantage with sheet molding is that there can be areas of varying density and mechanical properties from surface to center of the block formed if improper heat and pressures are applied. Another disadvantage of sheet forming is variance in bulk density of the resin can lead to inconsistency in the amount of powder in one region of the plate versus another. This will result in pressure differentials during forming from one area of the block to another, thus resulting in property differences. Also these materials are heat annealed for dimensional stability which may degrade the material.

Direct Compression Molding:

The direct compression molding process is used to form a finished component from raw resin. The concept of the process is similar to block or sheet molding except on a smaller scale. Instead of using flat platens, the plungers have the contour of the components being formed. The plungers are contained in a sleeve that has the same inner diameter geometry as the profile of the component being formed (Figure 7). The tooling may also allow for an insert, such as metal backing for an acetabular liner or tibial bearing, to be molded into the component.



Raw Resin Becomes Directly Molded Into a Finished Component.

Direct Compression Mold Tool.

Figure 7. Direct Compression Mold Tool and Component.

To mold a component, the bottom plunger is placed into the sleeve and a known weight of resin is poured into the mold. The top plunger is then placed into the mold. This is typically done in a controlled atmosphere. The mold, with the resin, is then placed into a press and cycled through a specified pressure and temperature profile. Once the component has cooled under pressure, it is removed from the mold and any excess material is trimmed. The component is essentially finished at this point.

This process has many advantages over the other processing methods. These advantages include control over surface roughness, control over resin quality, optimization of applied heat and pressure for each component configuration and reduction in capital equipment necessary to produce a component. The bearing surface finish is controlled by the roughness of the plungers used to produce the component. Better initial surface finishes may reduce the amount of debris generated during the “break-in” period. By consolidating the resin using an in-house process, the orthopaedic device manufacturer is able to choose only the highest quality lots of non-stearated resin as opposed to the resin converters selecting resin in ram extrusion. Since the area of the mold is much smaller than a sheet forming press, higher pressures and more uniform heat can economically be applied to counteract the possible differences in powder height and bulk density. The capital equipment required to produce direct compression molded components is less than that required to produce sheet or round stock. In addition to reduction in capital costs, the components do not usually require additional machining or annealing.

The disadvantages of compression molding are the initial cost of tooling, the difficulty of fabricating the mold tooling and the time required to manufacture a component. The mold tooling usually requires a large quantity of components to be fabricated to justify the initial costs. Also, the tooling is limited to the production of one specific component shape. In addition, the cycle time required to fabricate a component can be quite extensive, thus limiting the number of components that can be produced for a given work period across limited tooling.

Isostatic or Uniform Compression Molding:

In an attempt to improve consolidation and reduce residual oxygen in the material, isostatic or uniform compression molding was developed. This method of compression molding uses powder metal techniques to form bar stock, completed or semi-completed components. The technique is based on isostatic pressing technology making use of the concept of uniform application of pressure via a pressurized gas or fluid contained in a vessel.

The process consists of cold compaction into shape followed by vacuum sealing in a non-gas permeable container, then hot isostatically pressing the “canned” cold compact to fuse the resin. The major advantages of this process are uniform application of heat and pressure over irregular shapes and thicknesses and the ability to apply a known amount of pressure during the cool down cycle to all surfaces regardless of shrinkage. Schematics of the process are shown in Figures 8 and 9.

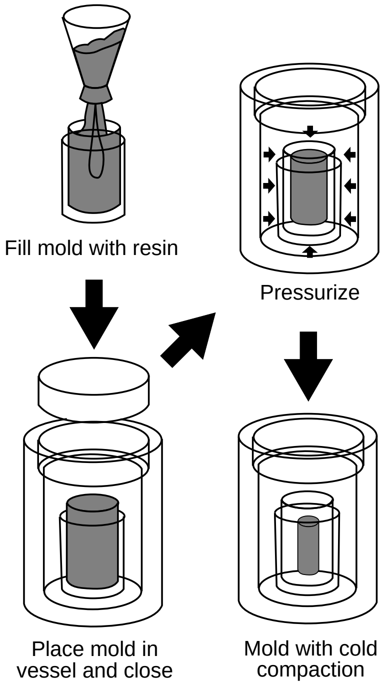


Figure 8. Cold Isostatic Pressing of UHMWPE Powder.

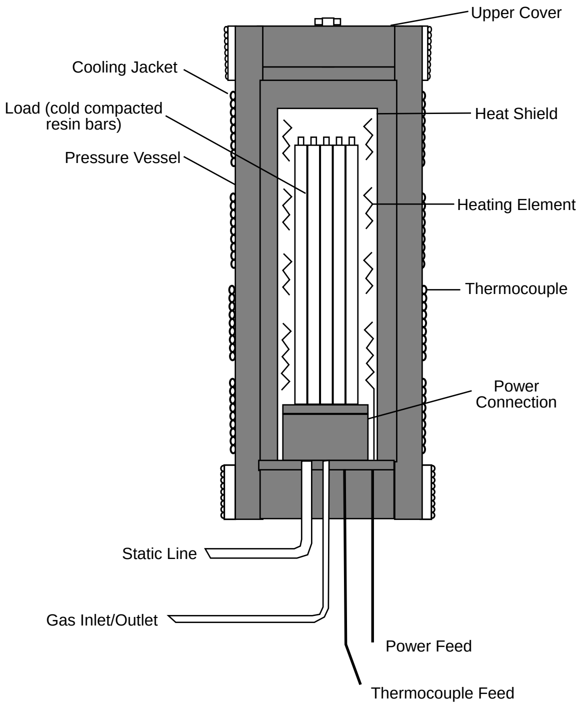


Figure 9. Isostatic Uniform Compression Molding Process.

The mechanical strength of this material is equal, or superior to, material produced by the other methods listed. In laboratory testing, in addition to mechanical strength, the material has shown to have superior wear characteristics to material consolidated by ram extrusion.[5] Another significant advantage to isostatic uniform compression molding is that the heated resin is not exposed to oxygen during processing, thereby reducing a possible source of oxidative degradation. Material processed in oxygen may perform differently than from non-oxygen processed polyethylene.[12]

Isostatic or uniform compression molding allows for specification of resin for each individual bar fabricated since it is a noncontinuous process. Also resins with very high molecular weights can be processed by this method without stearates or degradation experienced with other methods. It is also important to note this process is not shape dependent, which allows low cost fabrication of difficult to machine components as well as components that are too large to machine from commercially available stock. Since the material is formed using omnidirectional pressure, the final product has dimensional stability equal to annealed ram extruded bar and does not need additional thermal cycles, thus eliminating the degradation and increased oxygen absorption that can occur during annealing.

Effect of Consolidation on Mechanical Properties:

Figures 10 and 11 show examples of UHMWPE sections photographed by transmitted and darkfield lighting to show the consolidation of various methods of manufacturing. Figure 12 reveals the tensile strength relationship to consolidation. The results show that the more consolidated the material, the higher the tensile strength of the polyethylene.

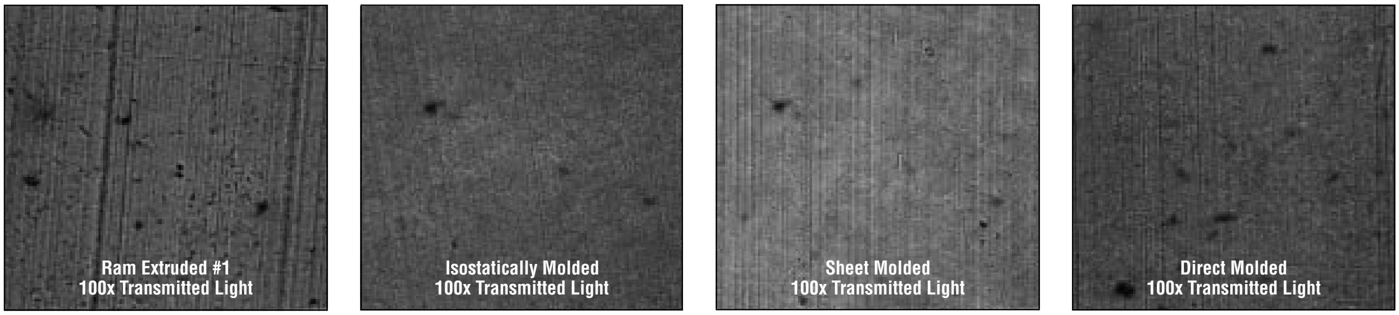


Figure 10. Transmitted Light UHMWPE Consolidation Photos.[5]

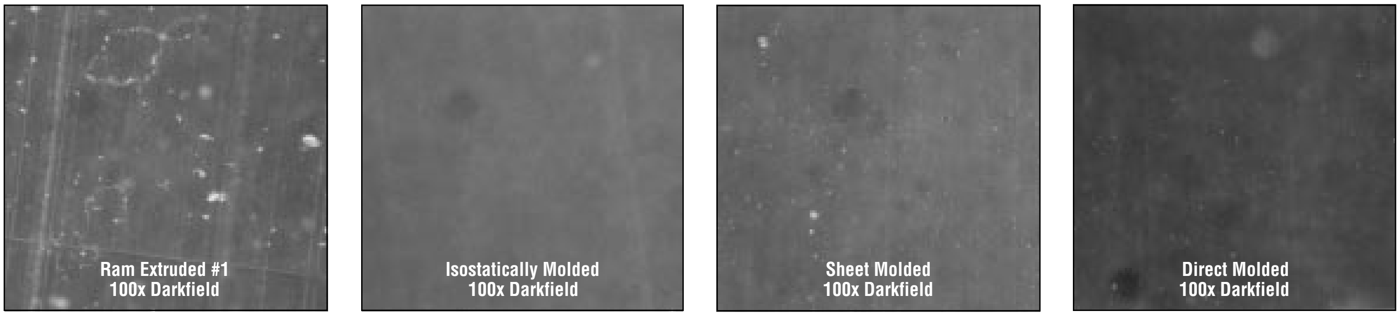


Figure 11. Darkfield Light UHMWPE Consolidation Photos.[5]

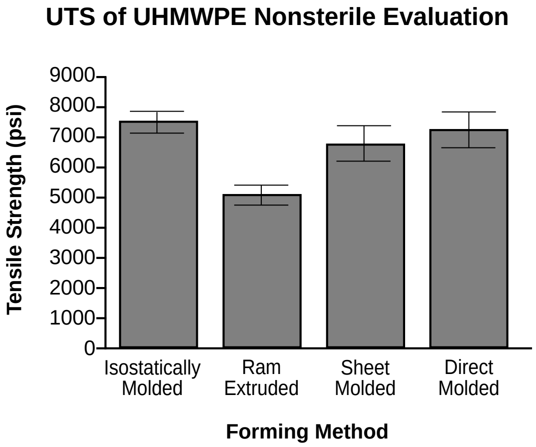


Figure 12. Tensile Strength vs. Consolidation of UHMWPE.[5]

These various manufacturing processes can yield quite different products. Figure 13 compares the differences in mechanical properties of UHMWPE processed using various methods.

Processing Method	Ultimate Tensile Strength (psi)	Yield Strength (psi)	Elongation* (%)
Isostatic Molding	7453 ± 409	3735 ± 104	620 ± 33
Ram Extrusion	5065 ± 306	3414 ± 82	506 ± 67
Sheet Molding	6812 ± 711	3103 ± 30	776 ± 65
Direct Compression Molding	7289 ± 652	3503 ± 78	570 ± 52

***Elongation based on crosshead displacement**

Figure 13. Mechanical Properties of UHMWPE Processed by Various Methods.[5]

The consolidation and excellent wear resistance of compression molded parts can be found in explanted components. Figure 14 shows a knee component implanted for nine years in a 58-year-old, active male weighing over 200 lbs. The one-piece molded tibial and metal-backed patellar components were direct compression molded and show little wear.

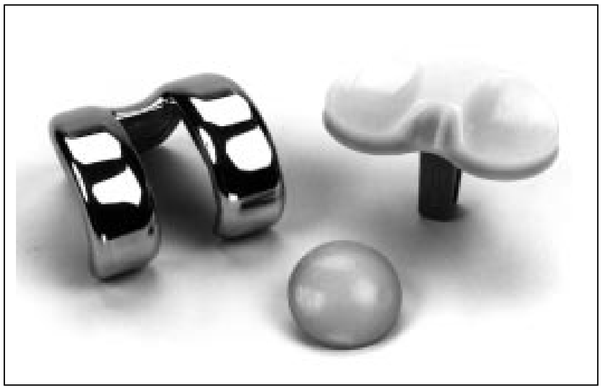


Figure 14. AGC® Nine-Year Retrieval.[5]

Consolidation of the material is critical to polyethylene performance in orthopaedic applications. ArCom polyethylene offers consolidated material through controlled resin selection and compression molding.

ArCom Polyethylene—A Solid Story

References:

[1] Eyerer, P., Ellwanger, R., Federolf, H.A., Kurth, M., Madler, H., "Polyethylene," *Concise Encyclopedia of Medical and Dental Materials*, Edited by D. Williams, The MIT Press, Massachusetts, c. 1990.

[2] Eyerer, P., "Property Changes of UHMW Polyethylene During Implantation—First Hint For The Development of an Alternative Polyethylene," *ANTEC*, pp. 230–232, 1985.

[3] Landy, M.M., Walker, P.S., "Wear of Ultra-High-Molecular-Weight Polyethylene Components of 90 Retrieved Knee Prostheses," *Journal of Arthroplasty* Supplement, pp. S73–S85, October, 1988.

[4] Stein, H.L., "Ultra High Molecular Weight Polyethylene (UHMWPE)," Engineered Materials Handbook, Vol. 2, p. 167-172, Engineering Plastics, ASM International, Metals Park, Ohio, 1988.

[5] Information on file at Biomet, Inc., Warsaw, Indiana.

[6] Hoechst, "UHMW Polymer Technical Data," November, 1982.

[7] Eyerer, P., Kurth, M., "Material Improvements of UHMWPE," *ANTEC*, pp. 1097–1100, 1986.

[8] Jensen, R.E., Collier, J.P., Mayor, M.B., Surprenant, V.A., "The Role of Polyethylene Uniformity and Patient Characteristics in the Wear of Tibial Knee Components," Implant Retrieval Symposium of the Society for Biomaterials, St. Charles, Illinois, September, 1992.

[9] Goodman, S., Lidgren, L., "Polyethylene Wear in Knee Arthroplasty," *Acta Orthop. Scand.*, 63(3): pp. 358–364, 1992.

[10] Wrona, M., Mayor, M.B., Collier, J.P., Jensen, R.E., "The Correlation Between Fusion Defects and Damage in Tibial Polyethylene Bearings," *Clinical Orthopaedics and Related Research*, No. 299, pp. 92–103, 1994.

[11] Bankston, A.B., Keating, E.M., Ranawat, C., Faris, P.M., Ritter, M.A., "The Comparison of Polyethylene Wear in Machined vs. Molded Polyethylene," *Clinical Orthopaedics and Related Research*, No. 317, pp. 37–43, August, 1995.

[12] Clough, R., "Radiation Resistant Polymers," *ESPT* 2nd Edition, pp. 667–708, Sandia National Labs.

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Biomet, Inc., Warsaw, IN 46580 (219) 267-6639

Biomet Ltd., Waterton Industrial Estate, Bridgend, South Glamorgan CF31 3YN, U.K.
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