Cryogenic Machining of Polymeric Biomaterials: An Intraocular Lens Case Study

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ABSTRACT

Machining of intraocular lenses (IOL's) is an acceptable industry practice, especially with rigid polymeric materials such as polymethyl methacrylate (PMMA). In recent years however, such rigid materials have lost market share to more biocompatible, softer materials. For softer hydrophobic materials, however, with glass transition temperatures (Tg) near or below room temperature, traditional machining is a challenging proposition due to the flexibility of the work piece at room temperature and smearing of the material surface due to cutting. Cooling approaches involving cold air guns and ice-blocking have been unsuccessful, since they do not lower the temperature sufficiently below the glass transition temperature of the material. In the present work, a new cooling approach involving Air Products' ICEFLY® cryogen delivery system is discussed. The ICEFLY® cryogen delivery system, which uses liquid nitrogen as a cooling medium, allows polymeric materials to be machined at a constant temperature during machining resulting in a predictable machining process and avoidance of cracking and other surface defects at extremely cold temperatures. Based on efforts completed to date, the technology has enabled the ability to machine a soft hydrophobic intraocular lens material to a surface quality comparable to the machined surface of more rigid hydrophilic intraocular lens materials.

INTRODUCTION

Use of polymeric materials is gaining increased acceptance in the biomedical industry, with expanded use of these materials within the human body. Machining has emerged as a cost effective option for these materials, since for small to medium sized batch production and/or specialized products, the cost of tooling for molds and extrusion dies becomes prohibitive. The mechanics of machining of polymeric materials with diamond cutting tools have been studied in detail, with better understanding of the tool wear modes, leading to optimum selection of tooling and cutting conditions [1 - 4].

Polymethyl methacrylate (PMMA) was used as the material for the first implanted intraocular lens (IOL), and has the longest application history amongst all optical polymers [5]. PMMA is a rigid, hydrophobic material with acceptable biocompatibility. Modern acrylic-based IOLs are copolymers and could be either hydrophilic or hydrophobic, based on the characteristics of the primary monomer. Silicone-based IOLs are made of polydimethylsiloxane, with the possible addition of phenyl groups.

The PMMA IOLs can be machined dry with acceptable surface finish~~,~~ due to the high stiffness of the material at room temperature. However, the industry trend is towards selection of more flexible polymers generally characterized by glass transition temperatures well below room temperature. The attractiveness of these polymers from a medical standpoint relates to smaller incision during implanting as well as better oxygen permeability with some of the newer materials. However, machinability is a very difficult proposition for these polymers, since softer polymers lack the stiffness at room temperature to be machined with an acceptable surface finish.

MACHINABILITY OF POLYMERS FOR INTRAOCULAR LENSES

The machinability of polymeric materials depend primarily on material characteristics (glass transition temperature [Tg], melt temperature [Tm], molecular weight and viscosity), as well as machining process conditions (cutting speed, cutting edge radius, tool angles and tool surface tribological properties). The stiffness of most polymers is highly dependent upon temperature. As polymers are cooled through and below their Tg, their stiffness increases dramatically, typically several orders of magnitude (Figure 1). The accepted notion is that the best machining performance and optimum surface finish occurs within a small temperature window around this glass transition region [6, 7]. This region, called cold flow, exhibits more elastic deformation characteristics, compared to higher temperature ranges, where the material stiffness is significantly lower and the material exhibits rubber-like behavior. Machining in the rubbery range is characterized by significant tearing and waviness in biopolymers. A temperature range lower than the cold flow region is characterized by transitional brittle/ductile behavior, material smearing and unacceptable surface finish (tough region). If the operating temperature goes even lower, extremely brittle and glassy behavior is exhibited by the biopolymers and machining is characterized by micro-chipping and possible fracturing of the part surface.

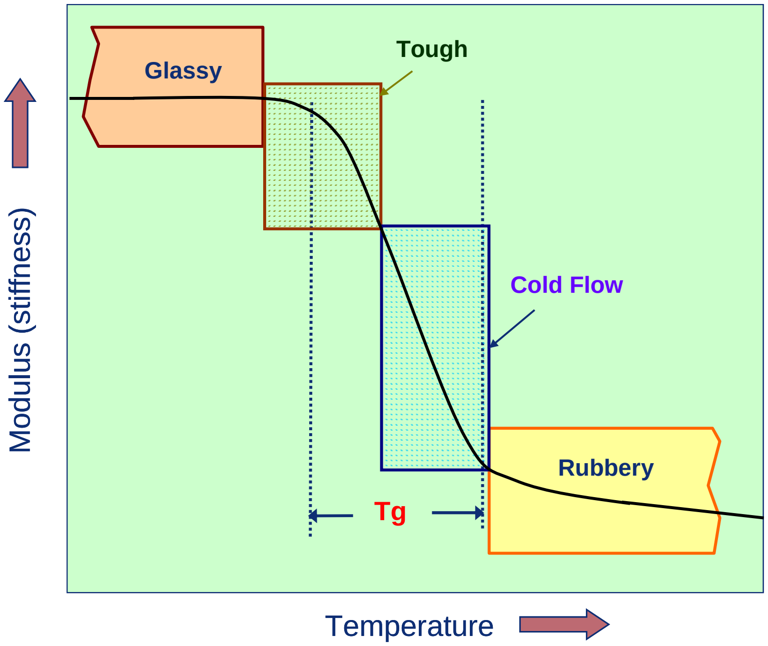


Figure 1: Typical stiffness curve for polymers with machinability regions

Based on the discussion above, the machining performance of a biopolymer is primarily determined by the relationship of its glass transition temperature to room temperature. For polymers like polymethyl methacrylate (PMMA), with a Tg of 110°C to 120°C, the material stiffness at room temperature is sufficient to enable machining. The frictional heat, generated during machining, increases the machining temperature to the cold flow range, generating acceptable surface finish (Figure 2). However, for polymers with Tg near or below room temperature (e.g. acrylic-based hydrophobic copolymer), machining is significantly more challenging, due to lack of material stiffness under ambient conditions.

The stiffness curve for typical acrylic-based hydrophobic polymers is shown in Figure 2. The glass transition temperature for such polymers range from -20°C to +20°C, placing the polymers at the borderline of cold flow / rubbery region at room temperature. If machining is performed without cooling, the temperature rise would cause the polymer to be well inside the rubbery region, with significant tearing and waviness in the finished surface. Controlled cryogenic cooling of the part immediately prior to machining would result in a temperature drop to a desired temperature range, such that the frictional heating during machining raises the temperature back into the cold flow region (Figure 2).

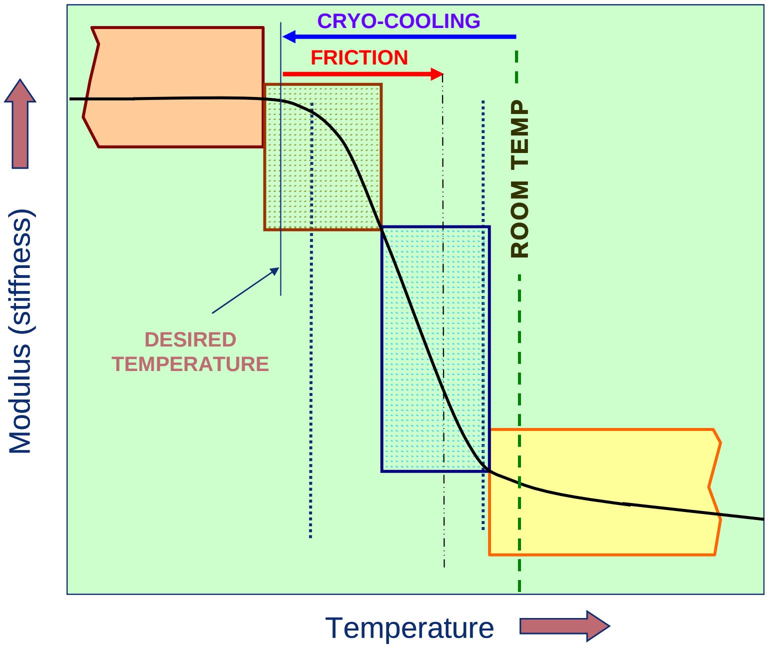


Figure 2: Typical stiffness curve for acrylic hydrophobic polymers showing need for cryogenic cooling during machining

CRITICAL COOLING OBJECTIVES FOR MACHINING SOFT BIOPOLYMERS

Soft biopolymers, with glass transition temperatures below room temperature, are mostly molded. Several non-cryogenic cooling approaches have been tried on these materials, to control part temperature during machining, but with extremely limited success. Current industry cooling options for low-Tg polymers include ice-blocking and cold air gun systems [8]. Cryogenic liquids have also been applied to cool polymeric materials, however, jetting of a cryogen on a part to be machined, without proper control of the phase of the cryogen, can rapidly reduce part temperature to well below Tg, which can cause part cracking or brittle fracture during machining. These approaches lack many of the key attributes necessary to ensure consistent specifications when machining soft polymeric materials. Providing a desired, stable part temperature range without overcooling or undercooling has been the primary challenge in coolant system design for polymers. The following objectives are critical in designing an effective, economical cooling system for soft biopolymers.

1. ***Provide a residue-free coolant***
   For machining biomaterials, the coolant should ideally be environmentally-friendly, biocompatible and residue-free.

2. ***Provide Fast Startup and Cooldown***
   For economical machining, the part surface/subsurface needs to be cooled down quickly to the desired temperature range. Typical cycle times for IOL machining are ~ 1 min. / side, and as such, cooldown time has to be in seconds.

3. ***Prevent Overcooling/Undercooling***
   Part overcooling can cause the part to be machined in the “glassy” region of the stress-strain curve, resulting in part cracking or surface damage from brittle chipping. Undercooling will cause smearing, tearing and part waviness. Maintaining the desired temperature range for a biopolymer is the biggest challenge for any cooling system.

4. ***Allow machining of various polymers with different Tg***
   For a cooling system to be universal, it should be able to handle polymers with different Tg by allowing desired temperature ranges to be set for each material.

The ICEFLY® cooling system for polymer machining is developed based on the above-mentioned objectives. The system uses a controlled mixture of atomized liquid and gaseous nitrogen, to impart cooling. Liquid nitrogen is an environmentally-friendly coolant that immediately vaporizes on impact, without leaving a residue on the finished part.

Previous academic and industrial attempts at cryogenic machining have been hampered by issues related to heat leaks and non-predictability of flow. For low-flow applications such as machining, heat input from the surrounding environment to the cryogen transfer piping and delivery system is a primary concern. Heat leaks can cause premature boiling of the cryogen within the delivery system thereby causing flow undulations. This can result in non-steady, pulsing and generally inconsistent flow and cooling of the workpiece. High noise levels can also develop from high gas velocities passing across a specified nozzle orifice when cryogenic liquid is prematurely vaporized to a gaseous state in a supply line due to heat leak. The ICEFLY® cooling system for polymer machining eliminates the problems associated with heat leaks and pulsed flow by using a patented temperature-controlled cryogen delivery system.

The schematic of the experimental setup is shown in Figure 3. Liquid nitrogen can be supplied from outside tanks or dewers. The ICEFLY coolant system is a PLC-controlled unit that can interface with the CNC lathe controls and deliver a controlled jet of the liquid nitrogen/gaseous nitrogen 2-fluid mixture through the nozzles. The patented delivery system (Figure 4) consists of a coaxial delivery line with an inner and an outer tube.

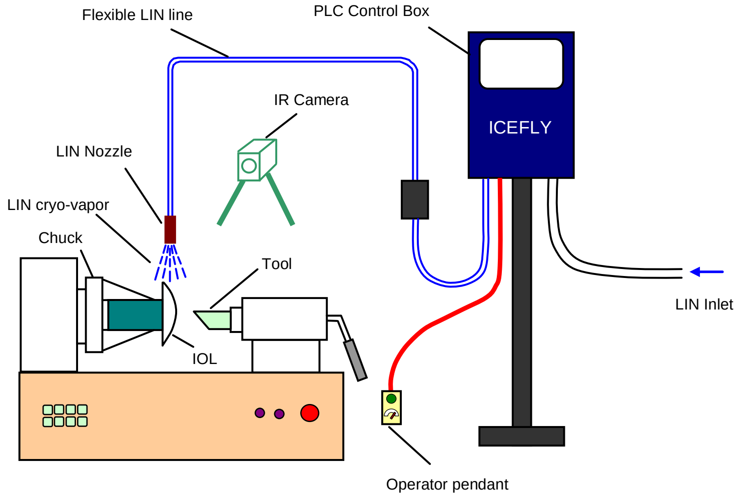


Figure 3: Schematic of the machining process

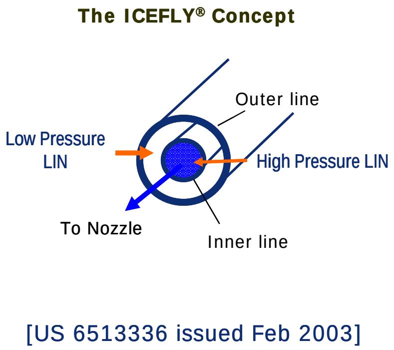


Figure 4: ICEFLY® delivery system

The inner line transmits the main flow to the nozzle, while the outer line provides refrigeration to the inner line. Since the temperature of liquid nitrogen is directly proportional to its pressure, the refrigeration in the outer line can be controlled by monitoring the volume and pressure of fluid flow in the outer line. Precise control of this refrigeration, in turn, allows precise temperature control of the 2-fluid flow in the inner line. In addition, by varying the amount of refrigeration, different temperatures can be set for the 2-fluid flow to machine materials with different glass transition temperatures.

EXPERIMENTAL PROCEDURE

Material Selection and Process Setup

Acrylic-based hydrophobic copolymer samples, in the form of 0.5" discs, were used for all machining tests. The tests were run on a manual Citycrown lathe (max speed 12000 rpm). Each part was glued onto a black polycarbonate arbor and mounted on the lathe. The cryogenic 2-phase flow was supplied using the ICEFLY cooling system. The temperature ranges for each sample were maintained using temperature feedback from a FLIR A40 thermal imaging camera and FSCap software.

Machining Process

A set of machining tests with varying levels of part temperature were carried out. Thermal images and videos of each process were recorded and analyzed. Final part surface was analyzed using a Zygo NewView optical profilometer, with 3-D part surface view, Ra and Rms as outputs. Chips were also collected and analyzed for each temperature condition.

RESULTS AND DISCUSSION

Effect of Cutting Speed (Relaxation rate)

Initial cutting tests were done at two cutting speeds: 3500 rpm and 12000 rpm. The surface roughness was found to be higher at the lower cutting speed. Material smearing was also visible at the lower cutting speed, while it was absent at the higher cutting speed.

The decrease in surface roughness with increasing cutting speed has also been observed in other polymers with low glass transition temperatures, like HDPE and LDPE [9]. For these low-Tg polymers, increasing cutting speed results in increased heat generation in the cutting process. While this reduces the shear flow stress of the material, the increased speed also results in strain rate hardening effect. Based on the time-temperature superposition principle for polymers, since the rate of applied external disturbance is higher than the relaxation rate of the polymer at the higher speed, the material behaves like a solid and undergoes elastic deformation. At the lower speed, the polymer had more time to respond, resulting in viscoelastic behavior, where the polymer exhibits both elastic and plastic deformation to varying degrees.

Effect of Cooling

Figure 5 shows the comparison of two intraocular lens surfaces, one machined with compressed air and the other with cryogenic fluid cooling. The air-cooled surface clearly shows significant tearing of the material and waviness in the finished surface, indicative of machining in the rubbery region. In contrast, the cryo-fluid-cooled surface is transparent and is free of any smearing or tearing of material.

Effect of Part Temperature

The glass transition temperature of the material tested, ranged from -20°C to +20°C. The hydrophobic polymer blanks were machined into final form at three different part temperatures (-7°C, -23°C, and -40°C). Since it was extremely difficult to control the cryo-fluid flow at a single temperature, a temperature range of ±5°C was maintained. Thermal images of the machining process were recorded, as shown in Figure 6. From a thermal imaging video, a difference in temperature of ~32°C was recorded between the part temperature and the machining temperature (chip temperature was ~25°C, while part temperature was -7°C).

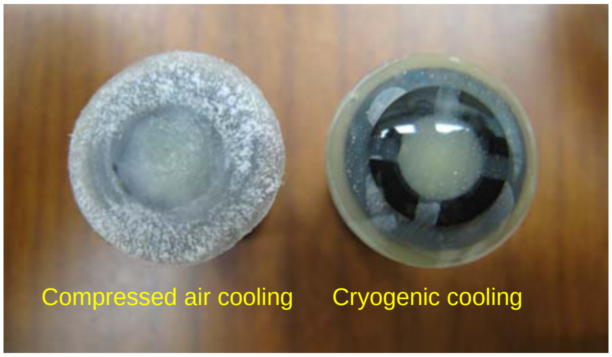


Figure 5: Comparison of IOL surfaces with air and cryogenic cooling

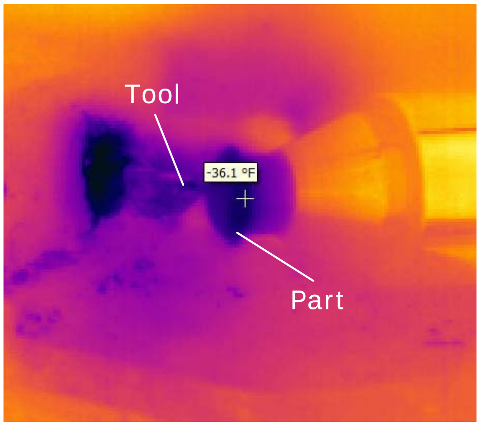
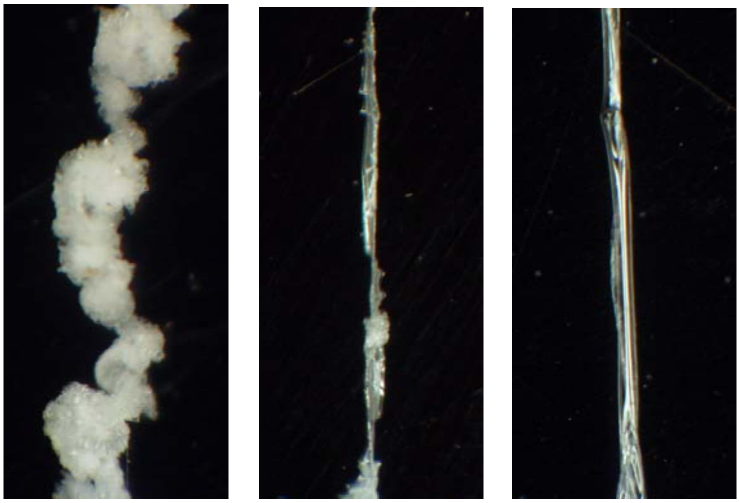


Figure 6: Thermal image of the part, showing instantaneous part temperature

Chips from the different machining tests were also analyzed to understand part temperature effects on the cutting process. Figure 7 shows the chips produced at the three different part temperatures. The chips produced at the warmest part temperature clearly show significant plastic deformation and “clouding”. This is possibly due to the fact that at the warmest part temperature, high frictional heating resulted in further softening of the material, thus reducing the deformation response time for the material and allowing the material to undergo plastic deformation. The higher frictional coefficient also resulted in "stick-slip" formation of chip on the rakeface, as indicated by the variable chip thickness. At the coldest part temperature, material was harder, frictional coefficient was lower and the material behaved elastically, as evident from the transparency of the chips produced. In the intermediate temperature range, where the material behaved viscoelastically, both forms of deformation were visible. Roughness and waviness of the finished surface also improved in the direction of the coldest temperature.

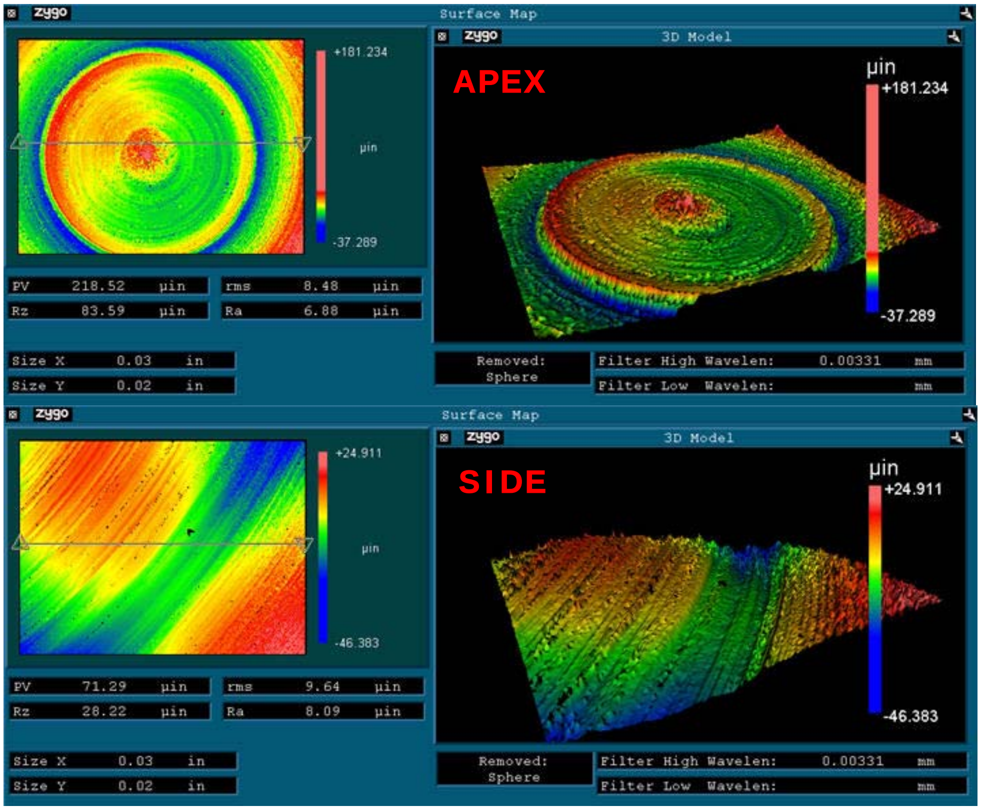
Figures 8 through 10 show the optical profilometry plots of the finished surface at the three tested temperatures. Two surface plots were generated for each sample, one at the apex and the other on the side. At the warmest temperature (-7°C), the average RMS roughness is about 9 micro-inches, and the roughness plots clearly show a surface waviness phenomenon. The hypothesis is that at -7°C, while the part surface is cold, the sub-surface is still warm and tool pressure causes this sub-surface to move, resulting in waviness. This is also supported by the fact that the waviness was most visible in the thicker sections of the part and wasn't visible near the edges. The low thermal conductivity of these polymers also contributes to the temperature differential between the surface and the sub-surface.



(a) -7°C (b) -23°C (c) -40°C

Figure 7: Chips produced at different part temperatures, showing varying degrees of deformation

At the coldest temperature, the waviness is completely eliminated and the average RMS roughness improves by about 40%. The improvement in surface roughness can be directly attributed to machining occurring in the cold flow region. As discussed earlier, the temperature differential recorded between the chip and the part was ~ 32°C. With the part temperature at -40°C, this would put the machining temperature inside the glass transition range (-20°C to +20°C) and in the cold flow region (Figure 2).



PV 218.52 µin
rms 8.48 µin
Rz 83.59 µin
Ra 6.88 µin
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Size Y 0.02 in
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Filter High Wavelen: 0.00331 mm
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PV 71.29 µin
rms 9.64 µin
Rz 28.22 µin
Ra 8.09 µin
Size X 0.03 in
Size Y 0.02 in
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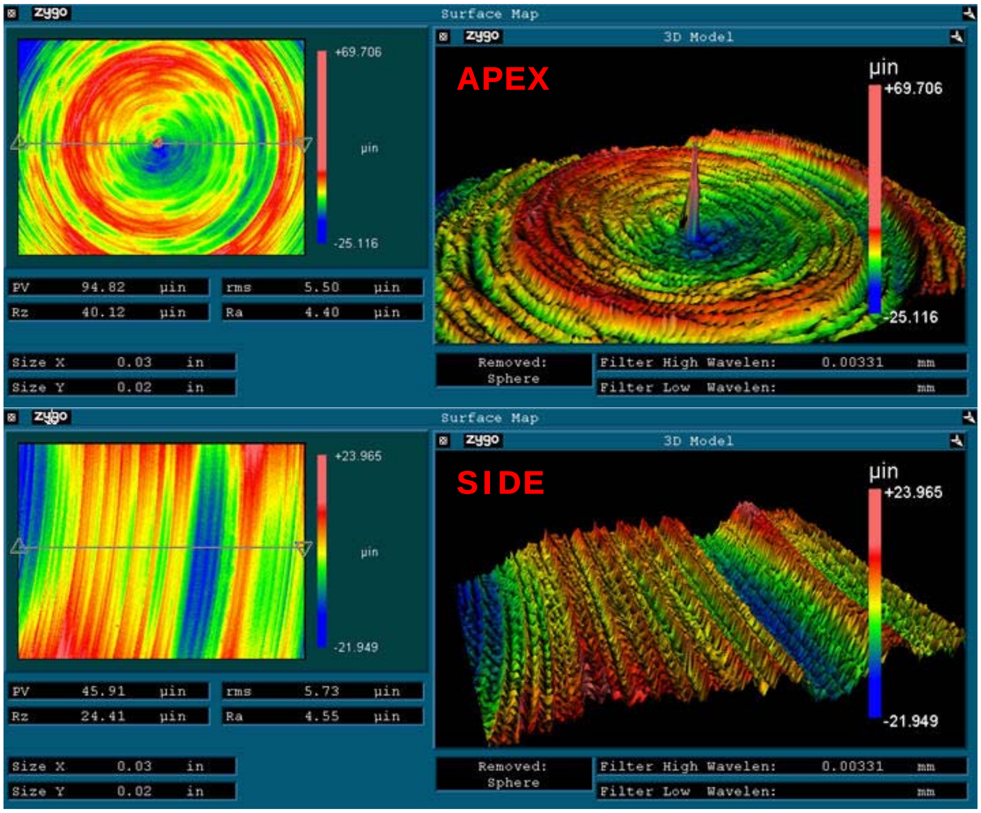
Figure 8: Optical profilometry of machined surface (part temperature -7°C)



PV 94.82 µin
rms 5.50 µin
Rz 40.12 µin
Ra 4.40 µin
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Size Y 0.02 in
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PV 45.91 µin
rms 5.73 µin
Rz 24.41 µin
Ra 4.55 µin
Size X 0.03 in
Size Y 0.02 in
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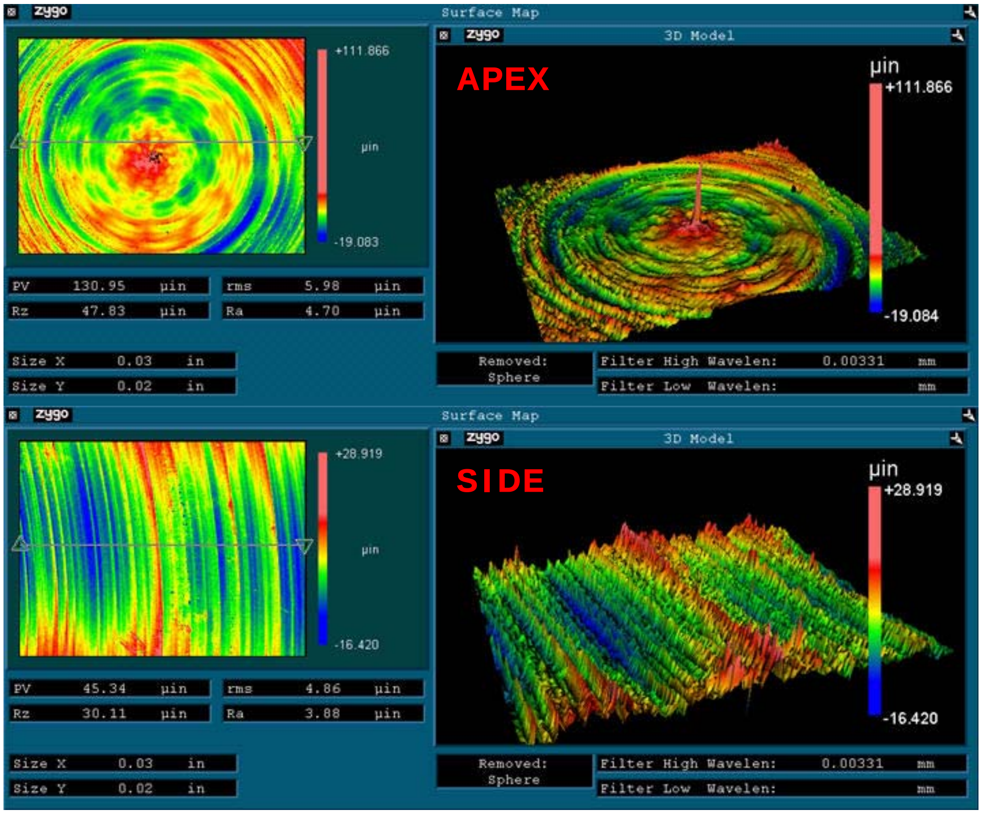
Figure 9: Optical profilometry of machined surface (part temperature -23°C)



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PV      130.95   µin     rms     5.98   µin
Rz       47.83   µin     Ra      4.70   µin
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Size Y   0.02    in
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Filter Low  Wavelen:             mm
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PV       45.34   µin     rms     4.86   µin
Rz       30.11   µin     Ra      3.88   µin
Size X   0.03    in
Size Y   0.02    in
Removed: Sphere
Filter High Wavelen:   0.00331   mm
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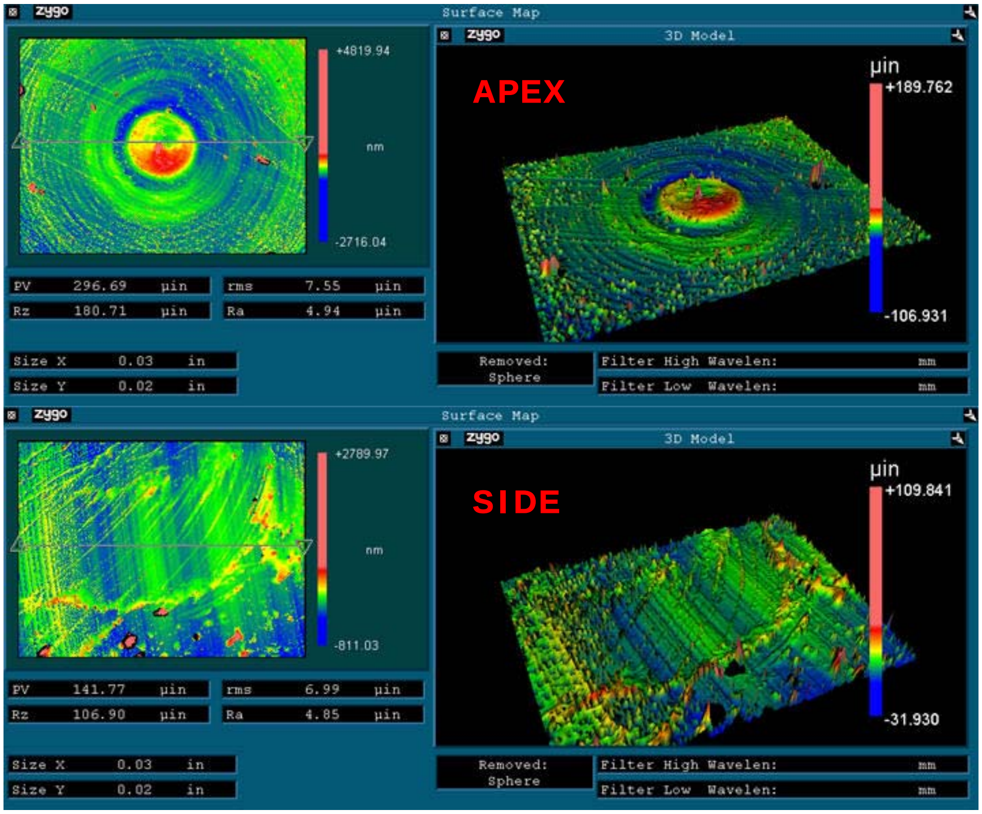
Figure 10: Optical profilometry of machined surface (part temperature -40°C)

Figure 11 shows the optical profilometry plots for a machined hydrophilic sample. This sample represents the current industry-accepted surface finish prior to polishing and was used as a benchmark sample for comparing the machined hydrophobic samples. Compared to the benchmark hydrophilic surface, the machined hydrophobic sample (Figure 10) shows an improvement of ~ 25% in RMS roughness, along with less smearing of material.

CONCLUSIONS

A new cryogenic cooling technology for machining of polymeric biomaterials has been described, with successful implementation in machining of acrylic-based hydrophobic polymers. For a polymer with low glass transition temperature, the ICEFLY® cryogenic cooling has been shown to provide controlled cooling to a desired part temperature, which allows machining in the cold flow region. The ICEFLY® cooling system has also been shown to deliver finish-machined surfaces with superior surface finish and reduced surface waviness, compared to compressed-air cooled samples. While the present testing was done on acrylic hydrophobic polymers, the flexibility and low-temperature capability of the ICEFLY® cryogenic cooling system may enable cost effective machining of other low-Tg polymeric materials that have heretofore been molded.



APEX:

PV 296.69 µin
rms 7.55 µin
Rz 180.71 µin
Ra 4.94 µin
Size X 0.03 in
Size Y 0.02 in
Removed: Sphere
Filter High Wavelen: mm
Filter Low Wavelen: mm

SIDE:

PV 141.77 µin
rms 6.99 µin
Rz 106.90 µin
Ra 4.85 µin
Size X 0.03 in
Size Y 0.02 in
Removed: Sphere
Filter High Wavelen: mm
Filter Low Wavelen: mm

Figure 11: Optical profilometry of benchmark hydrophilic machined surface

ACKNOWLEDGEMENTS

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REFERENCES

[1] Mamalis, A.G. and Lavrynenko, S.N., 2007, “On the precision single-point diamond machining of polymeric materials”, Journal of Mat. Proc. Tech., 181, pp. 203-205.

[2] Grabchenko, A.I., Verezub, N.V., Lavrynenko, S.N., Horvath, M. and Mamalis, A.G., 2000, “Precision cutting of optical polymer components for bioengineering applications”, Journal of Mat. Proc. Tech., 97, pp. 126-131.

[3] Gubbels, G., van der Beek, G., Hoep, A.L., Delbresssine, F. and van Halewijn, H., 1993, “Diamond tool wear when cutting amorphous polymers”, Annals of the CIRP, 53(1), pp. 447-450.

[4] Kopf, A., Feistritzer, S. and Udier, K., 2006, “Diamond coated cutting tools for machining of non-ferrous metals and fiber-reinforced composites”, Intl. Journal of Refractory Metals and Hard Materials, 24, pp. 354-359.

[5] Scholtz, S., 2006, “An ophthalmic success story: The history of IOL materials”, Cataract and Refractive Surgery Today Europe, Sept./Oct. 2006, pp. 61-62.

[6] Carr, J.W. and Feger, C., 1993, “Ultraprecision machining of polymers”, Precision Engineering, 15, pp. 221-237.

[7] Smith, E.F., 1989, “Single point turning of amorphous thermoplastic polymers”, MS Thesis, North Carolina State University, Raleigh, NC.

[8] AMCC Icing Plates (http://www.amcc.fr/pages-%20anglais/iol-GB.htm)

[9] Xiao, K.Q. and Zhang, L.C., 2002, “The role of viscous deformation in machining of polymers”, Intl. Journal of Mechanical Sciences, 44, pp. 2317-2336.