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Research on the Optimization of Key Technologies for Medical Balloon Formation Processes

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Abstract: A systematic study on key technologies and optimization schemes of biaxial stretch blow molding was conducted based on problems such as uneven wall thickness, performance fluctuation, and poor batch consistency in the industrial molding process of medical balloons. This paper describes the characteristics and core performance requirements of common materials for medical balloons, introduces the biaxial stretch blow molding process flow, key parameter control and quality stabilization technology, and proposes a full-process optimization method from aspects such as temperature field, pressure curve, stretching and blowing synergy, mold cooling, and post-treatment stress relief. The results show that after optimization, the wall thickness deviation, burst pressure dispersion and size drift of the balloon are significantly reduced, and the yield and molding stability are significantly improved, which can meet the requirements of large-scale production of high-end interventional devices.

Keywords: Medical balloon; Molding process; Key technologies

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1. Introduction

The rapid escalation of minimally invasive interventional medicine has driven the development of medical balloons towards ultra-thin walls, high burst pressure, and low compliance. The clinical and industrial aspects have put forward strict requirements for balloon size accuracy, mechanical stability, and batch consistency. Medical balloons are made from thermoplastic polymers and formed by biaxial stretching blow molding, which is a typical microscale thermally and mechanically coupled biaxial stretching process. Parameters such as temperature, pressure, stretching, and cooling are highly coupled, and even minor fluctuations can cause defects such as uneven wall thickness, contour deformity, and residual internal stress. This study combines industrial engineering practice with material forming principles to systematically optimize the key technologies of biaxial stretching blow molding, providing technical support for the high-precision and large-scale manufacturing of medical balloons.

2. Materials and performance requirements for medical balloons

Medical balloon materials should meet the requirements of biocompatibility, mechanical strength, flexibility and processability. Industrialized PEBAX, PA12, and TPU are mainstream, while temporary embolization balloons can use

PLA and PCL degradable polymers. PEBAX is mechanically stable and the preferred choice for high-end balloons; PA12 is creep-resistant but temperature-sensitive; TPU expands uniformly and is suitable for large-diameter cavities; Biodegradable materials have a narrow molding window and higher control requirements [1].

Medical balloons must meet clear size, mechanical and performance indicators. In terms of size, the nominal diameter deviation should be controlled within ± 0.1mm, and the length deviation should not exceed ± 0.1mm. The formula for calculating the coefficient of variation of wall thickness uniformity is:

$$C_V = \frac{\sigma}{\mu} \times 100\% \tag{1}$$

In the formula: C_V is the coefficient of variation of wall thickness uniformity, σ is the standard deviation of wall thickness, μ is the average value of wall thickness. The coefficient of variation should be no more than 10%, and the thinnest wall thickness should be no less than 0.05 mm; Mechanical bursting pressure should be no less than 1.5 times the nominal pressure, conventional coronary balloon bursting pressure should be no less than 1.2 MPa, high-pressure balloon up to 3.5 MPa, and cyclic fatigue should be able to withstand more than 10,000 cycles of charging and discharging pressure; In terms of performance, the coefficient of variation of radial expansion diameter should not exceed 5%, the expansion recovery rate should not be less than 95%, and the axial shrinkage rate should be controlled within 3%. At the same time, the requirements of no leakage, no fragmentation, and qualified biocompatibility should be met. The above indicators are the core basis for the design and optimization of the molding process (**Table 1**) [2].

Table 1. Molding characteristics and applicable scenarios of mainstream materials for medical balloons

Material types	Glass transition temperature	Molding temperature	Key molding characteristics	Typical applicable balloon
PEBAX	35 to 60 °C	165-178 °C	Uniform biaxial orientation and good toughness	Coronary, peripheral hypertension balloon
PA12	40-45 °C	170-190 °C	Temperature-sensitive and creep-resistant	Peripheral, renal artery balloons
TPU	- 40-0 °C	170-185 °C	Uniform expansion and good flexibility	Large-diameter cavity balloon
PLA/PCL	55-65 °C	155-165 °C	Narrow molding window, degradable	Temporary embolization balloon

3. Key technologies for medical balloon forming processes

3.1. Core process of biaxial stretch blow molding

Biaxially stretched blow molding is the core process for industrializing medical balloons, with axial stretching and circumferential blow-up as the core processes. The process includes tube pre-treatment, loading positioning, sectional preheating, stretching blow-up, mold bonding, pressure holding and cooling, demolding and post-treatment. Before production, the tubing is vacuum-dried to eliminate internal stress and remove moisture. After loading, it is fixed to a double-ended fixture and heated to a high elastic state. Through synchronous axial stretching and compressed-air expansion, the tubing adheres to the mold cavity under thermo-force coupling. The finished product is obtained after cooling, shaping, demolding and stress relief [3].

The total stretch ratio is the product of the axial stretch ratio and the circumferential blow ratio, calculated by the formula:

$$\lambda_{total} = \lambda_{axial} \times \lambda_{circum} \tag{2}$$

In the formula: λ_{total} is the total stretch ratio, λ_{axial} is the axial stretch ratio, λ_{circum} is the circumferential blow ratio.

The process stretch ratio is 1.5 to 5.0, the blow ratio is 2.0 to 8.0, the forming pressure is 0.1 to 0.8 MPa, and it is completed in seconds. The core difficulty lies in millisecond-scale timing matching and rate coordination between stretching and blow expansion at the microscale, with wall thicknesses of 10 to 50 μm. Mismatch is prone to quality defects.

3.2. Key process parameter control techniques

The quality of medical balloon molding is determined by the coupling of four types of parameters: temperature, pressure, stretching, and time, and the control accuracy directly affects batch consistency. Temperature is the basis for molding. The preheating temperature is controlled at 20 to 50 °C above the glass transition temperature of the material. The molding section temperature is 165–178 °C, and the mold temperature is 40–60 °C. The temperature control accuracy of high-end equipment can reach ± 0.3 °C. Excessive temperature fluctuations will cause uneven melt viscosity. Pressure determines the effect of blow-up molding. The blow-up pressure is 0.1 to 0.8 MPa, the holding pressure is 0.05 to 0.3 MPa, the pressure fluctuation is controlled within ± 0.005 MPa, and the pressure increase rate is stable. Stretching affects the orientation of the molecular chain. Double servo motors are used for synchronous stretching at a rate of 1 to 10 mm/s, and positioning and synchronization errors are controlled to within ±0.01 mm. Time control: The process sequence is connected; each link is precisely controlled in segments, and the system response time does not exceed 10ms to avoid parameter lag that could cause molding defects [4].

3.3. Key technologies for stable molding quality

Forming quality stability requires systematic assurance from pretreatment, process homogenization, and equipment control. Pipe pretreatment involves vacuum drying at 80 °C for 4 hours to eliminate internal stress and control outer-diameter deviation, thereby reducing dimensional fluctuations at the source. Temperature homogenization is achieved through segmented independent heating and axial compensation to maintain the axial temperature difference within ±0.4 °C. Tensile synchrony relies on dual servos and grating ruler closed-loop control to correct displacement deviations in real time. Pressure smoothing control uses a combination of proportional servo valves and accumulators to achieve a linear pressure rise and fall, reduce inner-wall wrinkles and contour deformities, and improve balloon-formation consistency [5].

3.4. Online detection and process control technologies

Online inspection and process control are essential for achieving high-precision molding. Industrial production lines adopt a collaborative architecture comprising a PLC and an industrial computer to achieve full-process closed-loop monitoring and automatic regulation. The online inspection system includes laser diameter measurement, ultrasonic thickness measurement, infrared temperature measurement, pressure and displacement acquisition units, which can monitor the expansion profile, wall thickness distribution, pipe temperature and stretching and blowing state in real time. The detection data is sent back to the control system in real time, and the PID adaptive algorithm corrects deviations in parameters such as temperature, pressure, and stretching rate, significantly reducing the time required for abnormal identification, effectively reducing batch fluctuations, and improving the production yield rate.

4. Optimization plan for key technologies of the medical balloon forming process

4.1. Overall optimization ideas

This optimization aims to improve wall thickness uniformity, burst pressure stability, dimensional accuracy and production yield, and builds a full-process optimization system from pre-treatment to post-treatment. Based on the thermo-force coupling deformation mechanism, to address the pain points such as temperature field, pressure curve, tension-blow matching, cooling and shaping, and internal stress relief, the technical bottlenecks were broken through means such as segmented control, dynamic adjustment, equipment upgrade, and closed-loop regulation. The optimization takes into account the feasibility and economy of the process. Based on the actual industrial design, parameter adjustment, process upgrades, and improvements to the detection closed loop are implemented to improve the quality and efficiency of balloon forming and meet the requirements of high-end interventional devices.

4.2. Precise control optimization of the temperature field

An uneven temperature field is the main cause of uneven wall thickness and performance degradation. Traditional resistance heating has a large axial temperature difference and is difficult to adapt to the formation of ultra-thin-walled balloons. The three-stage independent temperature-control structure is optimized by dividing the heating into the preheating, forming, and transition sections, with setpoints of 165 °C, 172 °C, and 168 °C, respectively. Each zone has independent PID control, and temperature control accuracy is improved to ±0.3 °C, eliminating deformation differences caused by regional temperature gradients. At the same time, short-wave infrared heating is used, the response time is shortened to 50 ms, the heating efficiency is increased by 40%, the axial heating uniformity is improved by 28.3%, and the melt viscosity fluctuation is reduced by 22.6%. The temperature field closed-loop correction was introduced, and the infrared thermal imager was used to collect the global temperature distribution in real time, automatically compensate for the edge temperature difference, and control the overall axial temperature difference within ± 0.4 ℃ to address the root cause of local overstretching and wall thickness deviation due to temperature inhomogeneity, reducing the coefficient of variation of wall thickness uniformity from 9.2% to 5.1%.

4.3. Dynamic optimization of pressure curves

Stepwise pressure loading can cause an increased risk of inner wall wrinkling, sudden wall thickness changes and cracking. The optimization uses a four-stage dynamic pressure curve to achieve smooth pressure transition and precise control. During the low-pressure pre-blow stage, the pressure rises linearly from 0 to 0.05 MPa within 0 to 0.1 seconds, eliminating wrinkles on the inner wall; During the rapid expansion phase, the pressure rises to 0.3MPa at a rate of 0.5MPa/s within 0.1 to 0.5 seconds to make the tubing fit the mold quickly and evenly; Maintain constant pressure for 0.5 to 3.0 seconds during the pressure stabilization molding stage to ensure full orientation of molecular chains and uniform wall thickness; During the slow depressions phase 3.0 to 3.5 seconds, the pressure drops linearly to 0 to avoid rebound deformation and stress concentration.

The formula for calculating the rate of linear pressure increase is:

$$\upsilon_p = \frac{\Delta p}{\Delta t} \tag{3}$$

Where: υ_p is the rate of pressure increase (MPa/s), Δ_p is the change in pressure (MPa), Δt is the time of pressure increase (s). The control system uses the fuzzy PID algorithm, and the pressure tracking error is controlled within ± 0.002 MPa. After optimization, the local overblow and underblow defects are reduced by 75%, and the overall wall thickness uniformity is improved by 12.5%.

4.4. Coordinated matching optimization of stretching and blow-up

Mismatched stretching and blowing timing and rate can result in uneven biaxial orientation, large mechanical differences in all directions, and poor folding rebound. Optimize by experimentally determining the optimal matching parameters, with an axial stretching ratio of 3.2 and a circumferential blowing ratio of 4.5, to achieve the best biaxial orientation uniformity and balance the axial and circumferential mechanical properties. Synchronous control of tensile and blow-up rates, with a tensile rate of 3mm/s corresponding to a blow-up rate of 0.4 MPa/s, ensures coordinated deformation of the material without lag or overload. The stretching lags behind the pre-blowing by 0.05 seconds in sequence to improve the problem of excessive wall thickness at the cone end and enhance contour consistency.

The balloon compliance calculation formula is:

$$C = \frac{\Delta D / D_0}{\Delta P} \times 100\% \tag{4}$$

In the formula: C is balloon compliance (%/MPa), ΔD is diameter change (mm), D_0 is nominal diameter (mm), ΔP is pressure change (MPa). After optimization, the difference in axial and circumferential mechanical properties was reduced from 18% to 5%, compliance was reduced to 4.6%, and the folding rebound rate was reduced by 35%, significantly improving the delivery and expansion performance.

4.5. Mold and cooling shaping optimization

Mold structure and cooling efficiency directly affect dimensional accuracy and residual internal stress. Uneven cooling of traditional molds can easily cause springback and out-of-tolerance. The optimized mold cavity is polished at the nanoscale, with a surface roughness Ra ≤ 0.01 μm to avoid demolding scratches. With conformal spiral cooling channels, the temperature difference of the cooling medium is controlled to within ±1 °C, ensuring uniform cooling throughout the entire area. The temperature is controlled by segmented cooling, and the cooling rates of different parts are matched across zones. Set the holding time to 2.5 seconds, based on the material's glass transition temperature, to ensure stable setting. After optimization, dimensional accuracy improves by 20.4%, internal stress decreases by 32.7%, diameter deviation remains within ±0.05 mm, and there is no obvious dimensional drift during long-term storage.

4.6. Post-processing and stress relief optimization

Residual internal stress after molding leads to dimensional deformation and burst-pressure attenuation during storage, thereby optimizing the vacuum annealing stress-relief process (**Figure 1**). The annealing temperature is set at 10°C below the glass transition temperature of the material, and the polyether block polyamide is controlled at around 125 °C, which can effectively relieve stress without changing the size structure. Hold for 30 minutes in a vacuum environment to prevent oxidation and discoloration. After holding, cool slowly in the furnace to room temperature to avoid new stress from rapid cooling.

The calculation formula for the internal stress relief rate is:

$$\eta = \frac{\sigma_0 - \sigma_1}{\sigma_0} \times 100\% \tag{5}$$

In the formula: η is the internal stress relief rate, σ_0 is the initial internal stress after molding, σ_1 is the residual internal stress after annealing. The internal stress relief rate of this process can reach 85%, the burst pressure stability is improved by 18.3%, and the dimensional drift during long-term storage is no more than 0.02 mm, significantly enhancing storage stability and service life (**Table 2**).

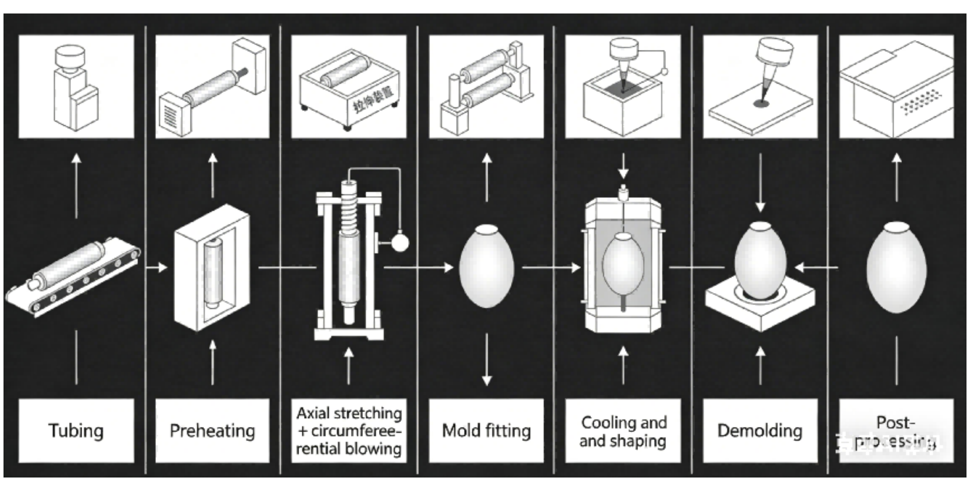

Figure 1. Schematic diagram of the biaxial stretch blow molding process for medical balloons.

Table 2. Comparison of the performance of the medical balloon molding process before and after optimization

Test indicators	Before optimization	After optimization	Improved effect
Coefficient of variation of wall thickness uniformity	9.2%	5.1%	Significantly improved
Blasting pressure dispersion coefficient	7.8%	3.5%	Enhanced stability
Yield rate	77.6%	96.2%	A significant increase
Diameter control deviation	+ / - 0.10 mm	+ / - 0.05 mm	Precision improvement
Residual internal stress	high	Reduce by 85%	Significantly reduced stress

5. Conclusion

To sum up, the core difficulty of biaxially stretched blow molding of medical balloons lies in the precise, coordinated control of multiple parameters in the thermoforce coupling process, as well as the systematic optimization of the temperature field, pressure curve, stretching and blowing matching, cooling and shaping, and post-processing. This study effectively addressed common industry problems such as uneven wall thickness, large burst pressure fluctuations, dimensional out-of-tolerance, and residual internal stress in traditional processes through technical means such as three-stage precise temperature control, four-stage dynamic pressure regulation, coordinated matching of stretch and blow, uniform conformal cooling, and vacuum annealing stress relief. After optimization, the balloon wall-thickness deviation and burst-pressure dispersion coefficient were significantly reduced, the production yield was significantly improved, and all indicators met the requirements for high-end interventional medical devices.

Disclosure statement

The author declares no conflict of interest.

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