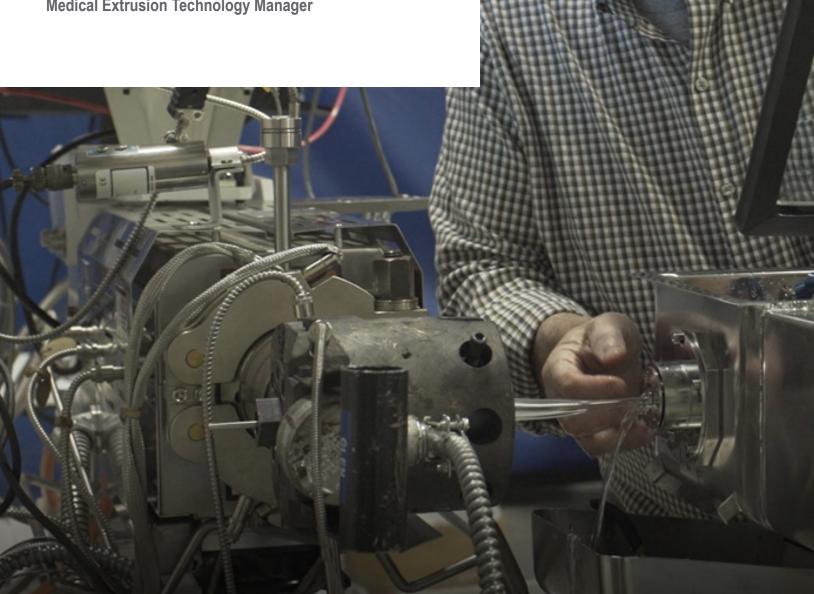
Micro Bore Tubing with a High-Speed Pressure Control Loop and Three Feed Throat Geometries Compared

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Consistent solids conveyance that is needed to control a process in a small extruder can be very difficult, mostly due to the size constraints of screw channel depth/root diameters needed to be able to withstand the torque requirements of the process versus the pellet geometries used by various manufacturers.

These factors can make it very difficult to control a process that requires tight tolerances of  $\pm 0.0005$ " or less in an open loop extruder. As well, process validation activities require stringent CpK/PpK requirements to ensure minimal variability in the medical device or pharma industries.

Some resins are historically notorious for being very difficult to control in small extruders (≤1"). It is not uncommon to lose solids conveyance completely with some of them, and many processors will use an off the shelf 2 or 3 groove feed section design to counteract this. There are problems associated with this practice, as unless the machine is for dedicated use the grooved section may not be appropriate for other materials/products/processes and with most extruders a feed throat can be difficult, time consuming and expensive to change.

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# **Common Solutions**

### Adding a Gear Pump

Adding a gear pump can add cost, shear, residence time and complexity to the process that needs to be accounted for. Die pressure control is normally used behind the pump, why not use it as the primary control for the process?

	Quanity	Estimated Cost	Total
Gear Pump	2	\$6,500	\$13,000
Flange In	2	\$2,000	\$4,000
Flange Out	2	\$2,000	\$4,000
Pump Drive	1	\$40,000	\$40,000
Transducer	1	\$1,200	\$1,200
Mounting	1	\$4,500	\$4,500
Temp Zones	3	\$2,500	\$7,500
			\$74,200

Cost example (general estimate and assumes two sets of hardware where needed):

Ongoing / Operational Costs:

	Potential Hours	
Setup Labor / Downtime	1	
Tear Down Labor / Downtime	1	
Pump Cleaning & Assembly	1.5	Not Downtime

Parts inventory as an ongoing operational cost could add tow or more labor / downtime hours per extrusion run that will directly reduce Overall Equipment Effectiveness (OEE).

### **Converting Supplier Material into Micro Pellets**

Converting material in micro pellets adds cost and additional process/drying heat histories to the raw material and does not guarantee success. Can be considered by some as "reprocessing" in an industry that does not normally support the use of reprocessed materials.

### Larger Machine

Many processors will revert to a larger machine then what the process output would call for (if not equipped with gear pumps) and most likely does not have the option for using micro pellets for reasons mentioned above. As an example, one might find a processor outputting <1lb/hr on a 1.25" extruder.

As well, the small size of the micro bore tubing limits the size of the tooling that can be used, especially when processing raw tubing stock for angioplasty balloons/stent delivery systems, neurovascular and peripheral applications. The majority of these components may require unique properties that necessitates the need for special cooling rates and limitations in area draw (ADR) for such things as proper balloon forming yields or reflow processing that can further hinder extrusion process design.

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## **Pressure Controls, Extruder Design**

Die (or head) pressure controls for smaller extruders have been in use for a few decades and have been provided by many vendors such as Dynisco, Gefran and Eurotherm as discreet units that can be retrofitted into just about any extruder. It has also available in the older versions of "HMI" controlled systems such as the old Barber Coleman Macco and Eurotherm EV3/4 systems.

Many of these systems over the years have worked well, but there were limitations due to system response times and were originally coupled with DC drives that were also slow to respond. With the proliferation of AC Vector drives and advances in electronics technology for discreet controls over the years there have been improvements with pressure control response times and capabilities (I have made it a practice to install pressure controls in every 12MM to 1.5" extruder I have been associated with over the past 25 or more years).

In general, discreet control systems today offers response times to pressure variances from set point is 50ms (not taking drive response into account). Based on the response time of the drive system, the pressure control loop would normally be muted through PID (or PI) parameters as so it would not overcorrect.

Today, with the cost reductions in servo drive technology small extruders can be equipped with servo drives without major spikes in pricing. An HMI touch screen with PLC control use high speed signal acquisition coupled with PC based CPU processing power to offer rapid responses for the control loop back to the servo drive.

With PLC controls combined with servo drive technology, the response time to pressure variations have been reduced to 30ms in total, including the drive response (over 40% faster from discreet units). This offers an even higher level of control than ever.

Also, since the modular designed extruders have quick change barrels (<6 minutes) and use feed throat inserts, it is simple and cost effective to be able to design feed throat inserts tailored to a pellet geometry to enhance system performance without having to compensate for the grooves in the screw design.

While offering many benefits logistically and operationally, modular designs are more expensive over non-modular units. Many non-modular extruders (such as the GEC Ultra Series) can still use feed throat inserts but can take many hours to complete a change out. Because of this it would be advantageous if using a grooved feed throat that it would not add additional torque and compression to the screw (or require a new design) if the machine is not for dedicated use. Also note that many grooved feed throat designs (as well as tangential) will also add axial deflection to small diameter screws, which will accelerate wear.

# Methodology

For the pressure control/feed throat experiment, 3 feed throat inserts were used without changing the process parameters to gauge their performance in the system. Closed loop control to the line puller was not used (though typical for medical extrusion lines) as so all variability shown was isolated to the extruder output.

Also, the initial process was purposely established as out of control. The snapshot of each experiment is shown using the function of diameter as opposed to actual pressure, as diameter is the critical output.

The three feed throat designs used:

- 1. Smooth bore
- 2. Typical/Standard 2 groove design
- 3. Special 2 groove designed specifically for the PA L25 without adding to the screw compression ratio or process torque required.

The smooth bore was initially used for baseline data without using a pressure control loop as an example of the typical output stability issues.

### **Material & Equipment**

**Material**: EMS Grilamid L25 PA12 Film grade (commonly used for medical balloons & catheter shafts)

#### Equipment:



Extruder - Graham Engineering modular extruder with Navigator X200 controls, <sup>3</sup>/<sub>4</sub>" barrel module, single flighted 17-4 screw with 40-60-80-200-40 screens and a Beckhoff 8.2Nm servo.



Water Trough - Conair vacuum tank (used as open tank)



Drier - Novatec NDM 5 SS Compressed air

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Laser - LaserLinc 6,000 Scan/sec per axis (scan averaging, 500 scans or 83ms) Triton 331 three axis head, Total View Software.



Puller/Cutter - Novatec Servo Controlled puller/cutter set to 95 FPM



Internal Air - AirLink Systems AC2 Servo Controller

### Tooling

Guill 812 Crosshead

0.082 Die, 0.090" Land 0.058" Tip, 0.150" Land

												Gap	Area
Mat'l	OD	ID	Tube Area	Wall	Die	Tip	Tool Area	Die LL	ADR	DDR	DDB	LGR	LGR
L25	0.03	0.022	0.000327	0.004	0.082	0.058	0.002639	0.09	8.077	2.733	1.037	7.5	34.10

Typical processing conditions for all experiements

Feed Throat	B1	B2	В3	Clamp	Adapter	X-Head	Die	Lb/Hr	Air Gap	Internal Air
100°	430°	445°	470°	470°	470°	465°	465°	0.95	7/8"	4"

1

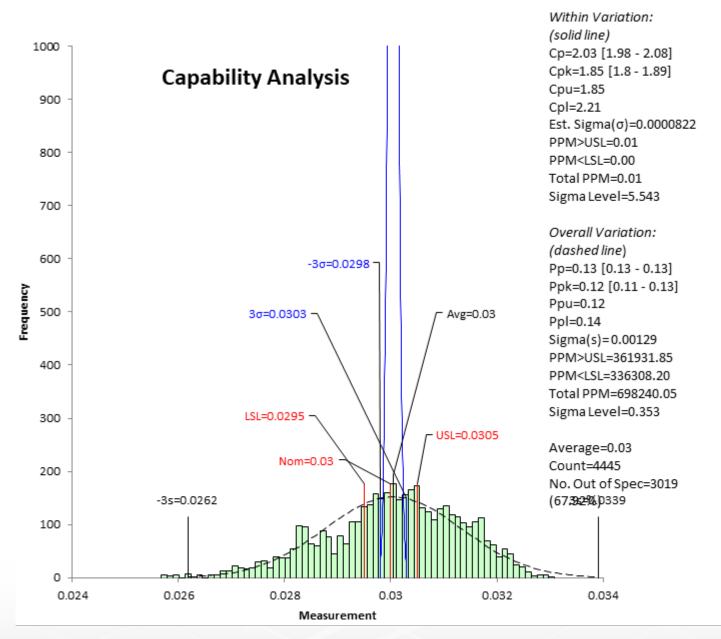
<sup>1</sup>Note: There was a die temperature swing of 3°F that created a noticeable sinusoidal pattern (frequency of temperature and diameter shift variations were approximately 1.5 to 2 minutes). This was due to the mismatch of type of heater (tubular with outer sheath on small mass). A puller feedback system tied to the laser gauge would have reduced the standard deviation in all cases. Currently designing a better heating system then the one provided (mica band/aluminum collar).

\*Baseline uncontrolled data was collected over a period of 30 minutes, 2 measurements per second captured.

\*All pressure loop control data was collected over 60 minutes minimum each at 2 readings per second captured.

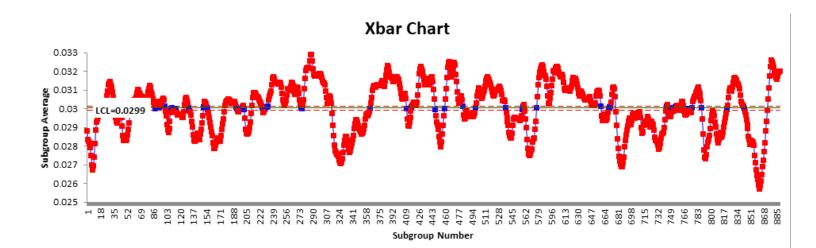
\* Data from laser output to CSV, imported into excel and generated with SPC for Excel (add on), Version 6.0.1.7 (spcforexcel.com)

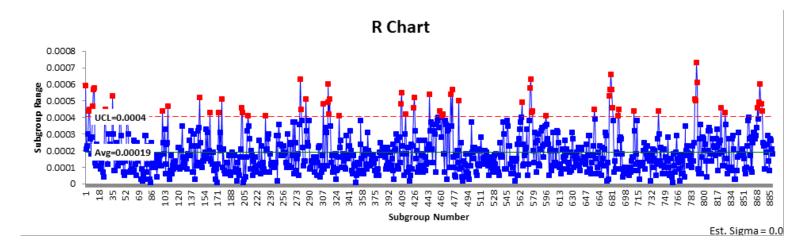




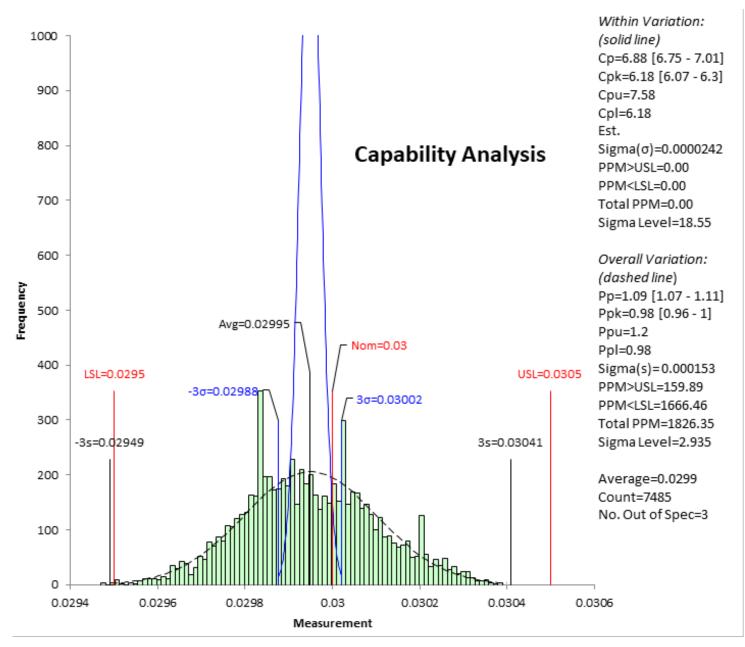
This process is out of control and would require a tolerance a decade higher than the  $\pm 0.0005$ " (and still would not pass validation efforts). Data within each subgroup of 5 readings (short term, 2.5s or 1.6 ft of tubing) was certainly not horrible, but the overall long-term performance of the process was. Note the Xbar/R charts on the next page.

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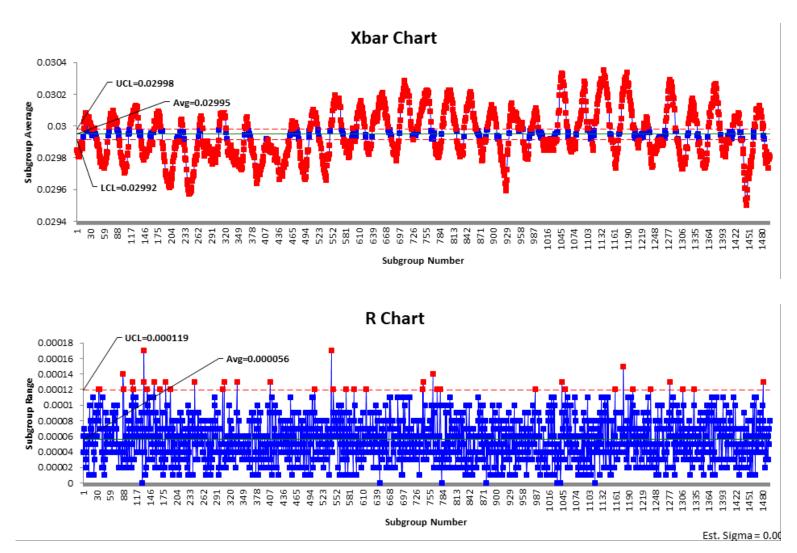




#### Analysis One Pressure Control Enabled, Smooth Bore Feed Throat

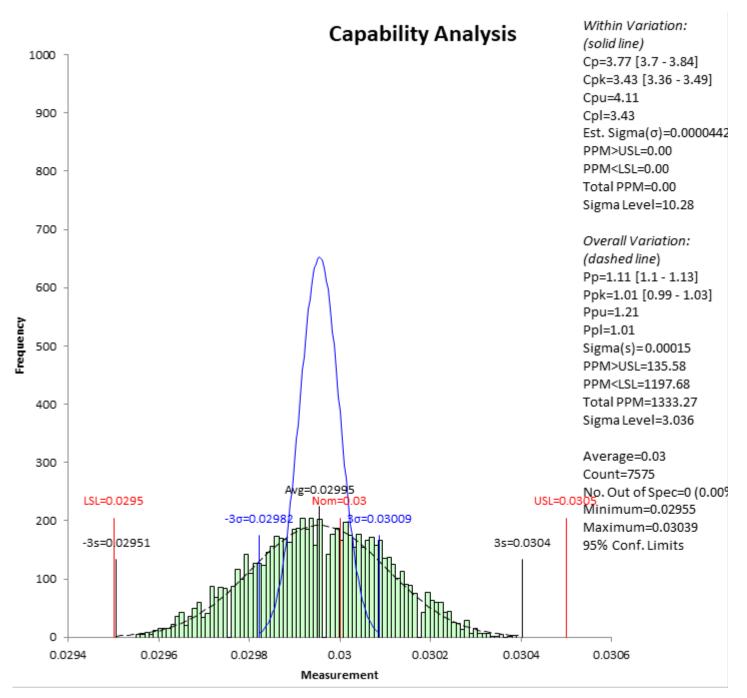


With the pressure control enabled, the variation with subgroups tightened considerably. Long term Pp and PpK also increased substantially. The only drawback to this feed throat design is that the process solids conveyance failed completely 2 times before data could be collected continuously for an hour and failed a 3rd time not long after the experiment was completed.

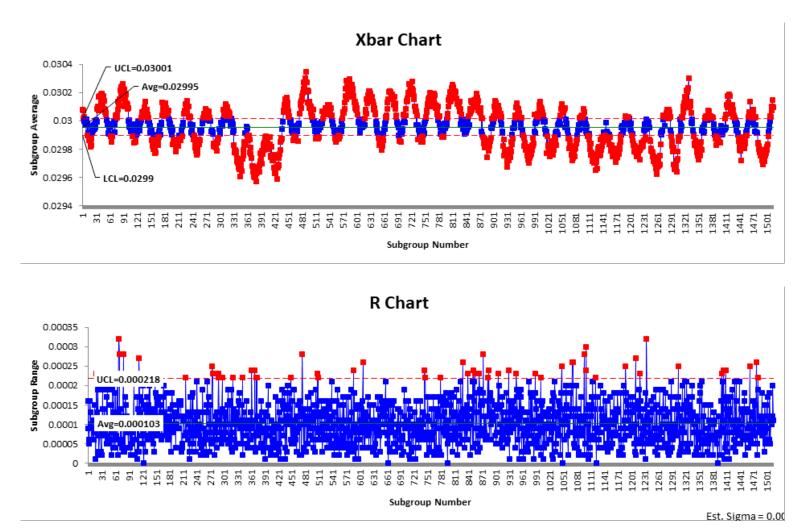


As you can observe the control limits/standard deviation have tightened up considerably. Much of the oscillation seen here can be attributed to the 3° swing in the die temperature (see footnote 1, page 8).

#### Analysis Two Pressure Control Enabled, Standard Two Groove Feed Throat



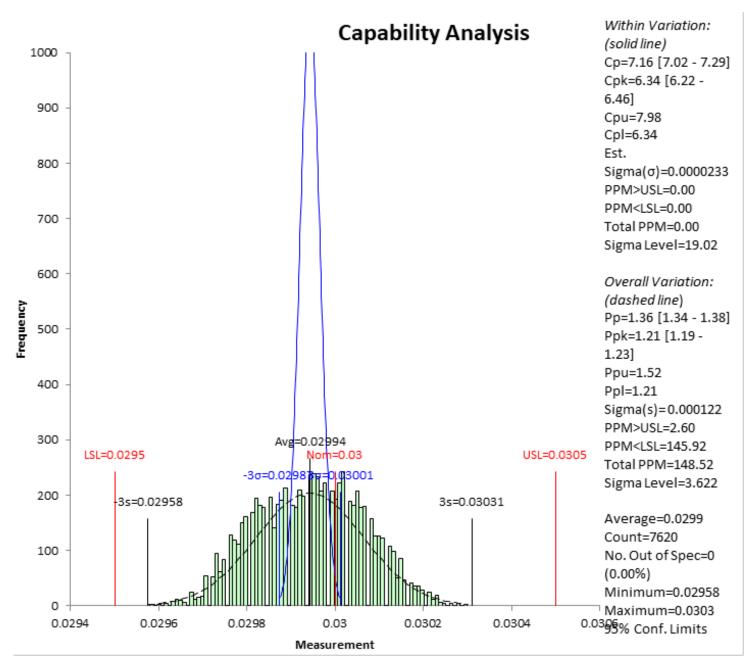
For this experiment, the variation within the subgroups increased over the smooth bore design, though the Pp and PpK are similar to the smooth bore insert (modest gain).



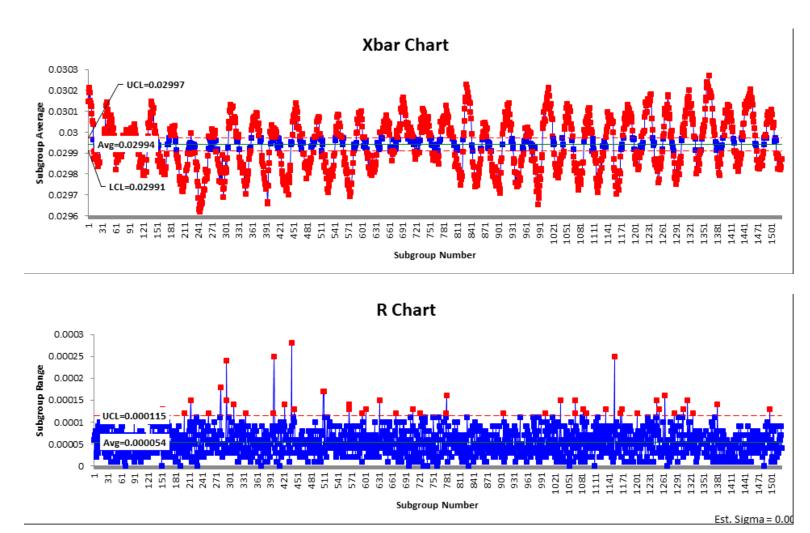
As with the histogram, the control limits for the Xbar chart are similar to the smooth bore, though the R chart shows an increase in the UCL of over 55%.

#### Analysis Three Pressure Control Enabled, Custom Two Groove Feed Throat

This feed throat insert was designed specifically for the L25 pellet geometry to enhance solids conveyance while minimizing additional torque and compression from the screw.



With this insert, the short-term variation decreased, Pp and PpK increased by 20% over the standard 2 groove insert.



The UCL and average for the R chart is reduced significantly from the standard 2 grooved feed insert. Some outliers noted due to water on the tubing found in the collection tray (not removed from the calculations).

# Machine Torque & RPM Comparison

	Extruder Torque	RPM	Process Average	Process Standard Deviation	Within Variation* CP	Within Variation* CPK	РР	РРК	
Smooth Bore No Control	10.5%	10.1	0.0300	0.00129	2.03	1.85	0.13	0.12	
Custom 2 Groove FT	9.1%	9.1	0.0299	0.00012	7.16	6.34	1.36	1.21	
Smooth Bore FT	10.5%	10.1	0.0299	0.00015	6.88	6.18	1.09	0.98	
2 Grooved FT	12.2%	7.5	0.0300	0.00015	3.77	3.43	1.11	1.01	
	*Variation within subgroups								

The custom insert:

a. Reduced the torque required from the drive system by 14% over the smooth bore and 25% over the standard 2 grooved design

b. Reduced the RPM required by the smooth bore by 10% and increased the RPM required by the standard 2 groove design by 18%

c. Did not affect follow up processes with other materials such as Pebax, PE and PUR that were processed with the custom design still in the machine, which will allow for the use of the design in non-modular machines without negatively impacting other processes.

d. The custom design does not allow for pellet accumulation in the grooves, making it easy to clean.

For this application due to the issues with solids conveyance failures I would rule out the use of the smooth bore feed liner unless it could be improved with further PD/screw design, which would take additional time and cost. Without additional information, I would select the custom designed feed throat to further develop the process.

# Conclusion

Pressure control is a viable option in lieu of adding gear/melt pumps to their extrusion. Today with high-speed systems and servo drives, one can take a process that is out of control and control it. I would like to emphasize this does not absolve one's responsibility to develop a process that is in control before initiating any closed loop controls (to be used as a band aid for a poor process). This is an example of what this type of control is capable of, the less you ask of the control the better off you will be in the long run.

As well, feed throat design is an important aspect that affects the behavior of the process. Grooved feed throats have their place and modular systems with feed inserts will make changing the design easy and fast, though specialty designs can be used that minimize the impact to the process and components while not requiring it to be changed for other uses, which makes them a better option then standard grooved designs for non-modular machines.

## **About the Author**



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43 years in the extrusion industry with a focus on medical products and processes for over 39 years.

Multiple levels of engineering, engineering management and company management in the medical extrusion field with various contract manufacturers and medical device OEMs.

10 product and process patents.