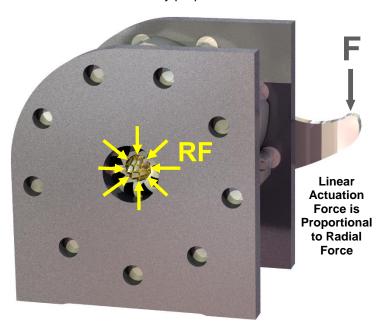




In a radial compression process, such as stent crimping, balloon compression, marker band precrimping, etc, one of the most fundamental questions is: **should we control the diameter or the radial force?** This paper examines this question in a simplified way that is useful for understanding.

It's not possible for the machine to control the diameter and force simultaneously. The process engineer must choose one or the other. If the machine controls the force, then the product (balloon, stent, etc.) controls the diameter. If the machine controls the diameter, then the product controls the force.

In this paper we will use Actuator Force and Radial Force interchangeably with no loss of meaning. In most Blockwise machines, Actuator Force and Radial Force are linearly proportional to each other.



When a radial compression mechanism closes on a product, it moves in the closing direction, eventually reaching a steady-state compression condition with unchanging diameter and radial force. Let's think about what determines those values of diameter and radial force in six different cases.



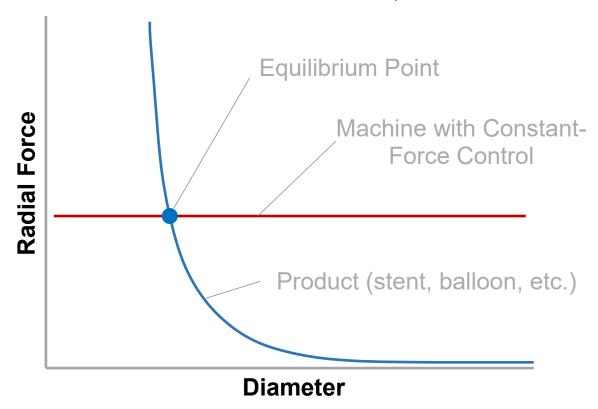
1. **Force-controlled machine.** When the machine is creating a force-controlled process step, then the compression mechanism will close until there is a force balance: The outward radial force from the product equals the radial force applied by the machine.

The product being compressed has its own diameter-vs-radial force characteristic; an example is shown in blue on the graph.

The machine in steady-state provides a constant force as shown in red on the graph. This is commonly achieved in one of two different ways:

- a. Actuating the mechanism using an air cylinder with a constant, regulated pressure supply.
- b. Actuating the mechanism with an electric motor, through a force sensor, and applying a closed-loop control that modulates the motor so that the measured force equals a setpoint.

In the force-controlled machine, the steady-state force balance is reached at the <u>blue</u> point on the graph, where the machine's force-vs-diameter characteristic crosses the product's force-vs-diameter characteristic.





2. **Diameter-controlled machine.** When the machine is creating a diameter-controlled process step, then the compression mechanism will close to a set diameter.

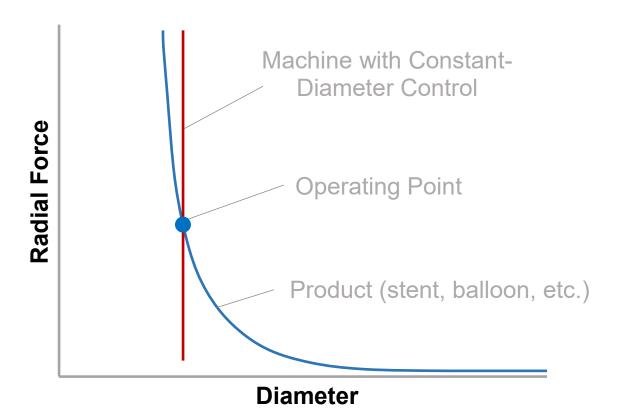
The product being compressed has its own diameter-vs-radial force characteristic; an example is shown in blue on the graph.

The machine in steady-state provides a constant diameter as shown in **red** on the graph. This is commonly achieved in one of two different ways:

- a. Actuating the mechanism using an air cylinder with supplied with plenty of pressure to overcome the outward force from the product, and let the mechanism hit an adjustable mechanical stop ("hard stop").
- b. Actuating the mechanism with an electric motor, through a force sensor, and commanding the motor to a position (possibly using encoder position feedback).

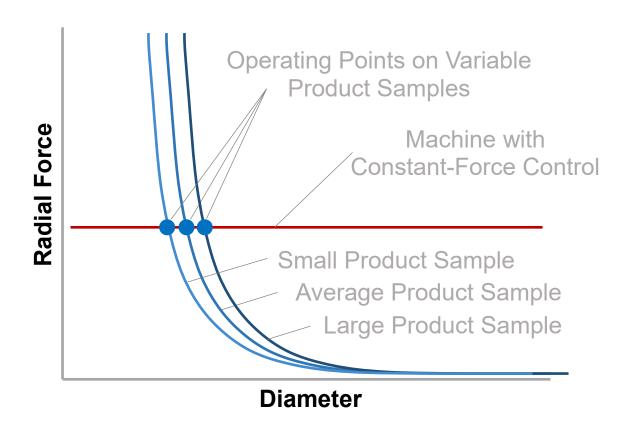
(Actually, in both cases a. and b., there is some compliance in the mechanism or linkage that prevents the actual diameter from being independent of force, so the red line is not exactly vertical. Some machines are better than others at creating a constant diameter, independent of force. This is a big advantage of the electrically-actuated Blockwise machines.)

In the diameter-controlled machine, the steady-state operating point is the blue point on the graph, where the machine's force-vs-diameter characteristic crosses the product's force-vs-diameter characteristic.



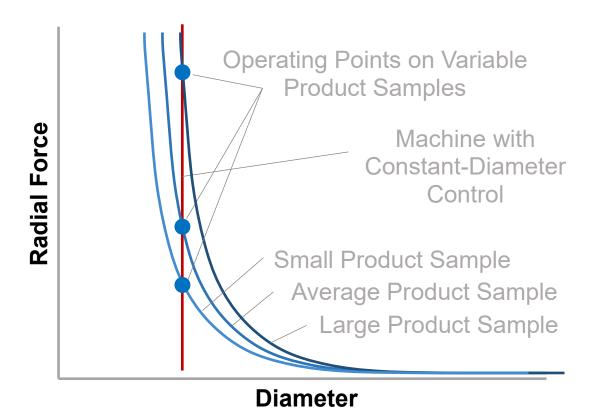


Force-controlled machine with product variability. When the machine is
creating a force-controlled process step and the product has variability, for example in the cross-sectional area
of its plastic extrusion, then the steady-state force balance point will also vary, but the surface pressure on the
product varies only slightly.





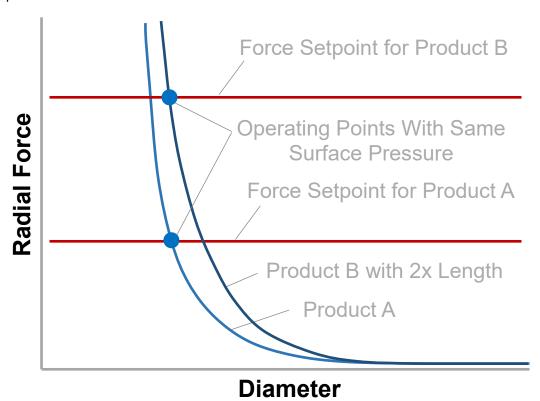
4. **Diameter-controlled machine with product variability.** When the machine is creating a diameter-controlled process step and the product has variability, for example in the cross-sectional area of its plastic extrusion, then the steady-state operating point moves significantly on the product's characteristic curve, causing significant variability of the surface pressure on the product.





5. Force-controlled machine with different product lengths. In this case the machine is creating a force-controlled process step, and one product (for example, a balloon/stent combination) is the same model as another but twice the length. Using the same force setpoint on both products results in about half the surface pressure on the longer product. Doubling the force setpoint on the longer one results in about the same surface pressure on the two products.

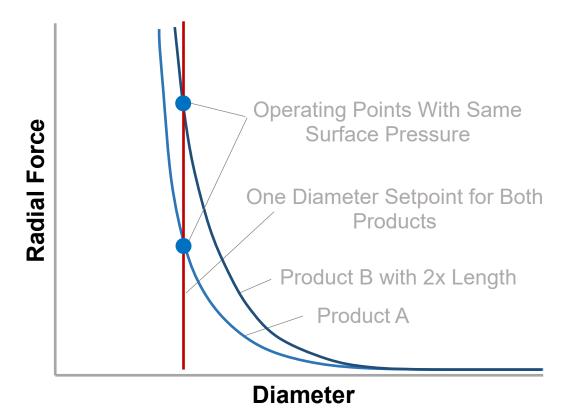
Therefore, different process settings (recipe) may be needed for the two products, which is less convenient and more prone to mistakes.





6. **Diameter-controlled machine with different product lengths.** In this case the machine is creating a diameter-controlled process step, and one product (for example, a balloon/stent combination) is the same model as another but twice the length. Using the same diameter setpoint on both products results in about the same surface pressure on the two products.

Therefore, the same process settings (recipe) may be used for the two products, which is convenient and less prone to mistakes.



Conclusions It should be clear from analyzing these cases that shape of the diameter-vs-force characteristic of the product influences the results and conclusions. In general, when crimping on a very flat part of a diameter-vs-force curve, the results will be more consistent with a diameter-controlled machine. When crimping on a very steep part of a diameter-vs-force diameter curve, the results will be more consistent with a force-controlled machine.

We can also make some general statement about the relative advantages and disadvantages of each control method when the process is operated on a steep diameter-vs-force characteristic.

Force Control	Diameter Control
Less sensitive to product variability	More sensitive to product variability
More recipe changes required to cover different product lengths	Different product lengths can use the same recipe

There are also other differences that are specific to certain machine models. For example, on pneumatically-actuated balloon wrapper compression stations, the diameter control is more difficult and error-prone (set with a stop-screw) than force control (set as a pressure setting in the controller).



For typical balloon expandable stent crimping, the process usually operates on a somewhat steep part of the diameter-vs-force curve, but the product variability (and diameter control precision) is usually good enough that good final product variability can be achieved with diameter control. There are many successful examples of both diameter and force controlled stent crimping processes.