Next level precision: How the latest developments in grinding are pushing boundaries

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Introduction

Wire components are increasingly important in the construction of medical devices and are, in fact, crucial to the success of major life-saving procedures. Take, for example, guidewires - the thin, flexible medical wires that are used to guide larger instruments such as catheters into specific positions within the human body and are fundamental to peripheral, coronary and neurovascular procedures.

As surgical techniques become increasingly sophisticated and devices become smaller, the precision manufacturing of smaller wires will become more important in determining whether a medical procedure is successful.

Medical wires need to exhibit more precise tolerance in the future, and micro-grinding is the technique that is essential in the advanced manufacturing of these components. It is an adaptable technique that is replacing standard machining practices in many applications, as it can be used to create highly specific characteristics in increasingly complex medical wire products.

Though the principle has changed little over the years, advances in areas such as computer numerical control (CNC) equipment are helping to ensure the quality of the smaller and more precise components that are required to reach into veins, arteries and other minute parts of the human body.

As the number of minimally invasive surgeries grows year by year, driven by lower associated costs, improved healthcare infrastructures in developing countries, shorter recovery times, and the reduced impact on the patient, manufacturers will need to produce precision components at scale.

The emergence of specialized medical guidewires is key in enabling this shift but in reducing the scale of the product, the need for precision and accuracy increases. Specifications for tolerances are getting tighter, for example, as designers and engineers try to make devices as compact as possible, testing the limits of both machines and materials.

Here, we examine how advances in the grinding process are helping manufacturers to meet the stringent requirements of the medical industry, and why grinding affords manufacturers a level of accuracy and finish quality that other methods cannot achieve. With the help of specialist grinding company Custom Wire Technologies (CWT), we will look at the key advantages that the latest developments in grinding can offer modern-day medical devices, and the role it has in the future of minimally invasive surgery.

From small to smaller

Wire grinding is a robust technique that nevertheless needs to keep evolving, due to the mounting pressure on manufacturers to produce even smaller components suitable for minimally invasive surgeries with faster patient recovery times. As the scale of medical devices diminishes, the need for precision and accuracy increases.

As specifications and tolerances reach their maximum capability, manufacturers need to further refine their processes to accommodate the next generation of devices.

"Grinding can achieve finishes, diameters, and tolerances that other methods, like milling and turning, are not able to achieve," says Jim Boldig, director of engineering at CWT. "It is the preferred method when the size of the devices is critical to functionality. The smaller the device becomes, the greater care and precision must be taken."

"Grinding can also create features that normal machining operations cannot achieve due to the small scale of wire sizes," he adds. "CWT is often working with wire diameters under 1.0mm and the majority of guidewire applications are using material smaller than 0.5mm in diameter. Grinding is an adaptable technology that can be used in lieu of standard machining practices. This is especially true when sizes are reaching the minute scale of the human anatomy."

Currently, grinding is used to create many common components, including guidewires, core wires, mandrels, orthopedic pins, and hypotubes. These can be made using a wide range of materials, among them stainless steel, nitinol, titanium, magnesium and aluminum. In each case, the key theme is to use grinding techniques to create components that can reach any area in the body, including the brain, where a wire must pass through vasculature which is smaller than those associated with the heart to deliver a treatment.

"To achieve the performance criteria and size requirements the materials must be processed to smaller sizes," explains Boldig. "Depending on the application, grinding can make the part more flexible or create a unique fitment to an assembly or specific feature. Core wires for guidewire applications usually have a grind profile to meet anatomically correct positions. This allows the end user to manipulate the end wire with precise movements."

"Furthermore, grinding complex geometries on orthopedic wires and needles addresses specific design criteria," he adds. "An ortho wire may need a sharp trocar or threads, while a needle may need a bevel tip or side port. Grinding is the one of the only reliable methods to make devices smaller. As engineers and designers continue to work to make products better and more efficient, we will continue to see the trend to make products smaller, which creates the need for better controls and accuracy."

Currently, CWT can adjust diameters down to 0.00025mm. The company is capable of grinding hypotubes to achieve wall thickness less than 0.025mm, which suits customers seeking to place a stent in the brain and using the extremely thin wall thickness to aid in that placement.

"The industry has been focused on producing smaller components, driven by reducing patient recovery times by making the operation less invasive," says Boldig. "The majority of the time we are successful in our adjustments to make smaller components, but there are some occasions where we cannot meet the specifications required. So, we consult with the customer to determine which direction to head, and we find a common ground where we can still successfully meet the requirements."

"We are also closing in on the threshold of the human capability to see what we are producing," he adds. "CWT possesses inspection systems which map diameter over distance to visually represent what is being produced. Without this type of inspection, it would be very difficult for the operators to understand what is being produced and to what level of quality."

A growing market for smaller wires

In a world where sedentary lifestyles and unhealthy habits are impacting the health of millions of people, an increase in chronic medical conditions and related surgeries is expected. Consequently, the market for surgical guidewires is expected to grow to $2.19bn by 2027.

According to Brian Hicks, MSc, medical analyst at GlobalData Healthcare, the Covid-19 pandemic has also played a role in boosting the growth of the market. It led to an unprecedented number of postponed and cancelled elective surgical procedures in 2020, substantially impacting the general surgery devices market, especially in its worst hit months of April and May. While many of the general surgery device markets returned to pre-pandemic sales volumes and growth rates during H2 2020, the exacerbated backlog of elective procedures due to the pandemic continued to fuel demand well into H1 2021.

Analysis of market trends in 2022 reveals that general surgery device sales have also continued to increase in both revenue and sales unit volume and are forecast to maintain this growth pattern well into 2023. In fact, GlobalData reports that the global general surgery devices market will reach 35 million USD next year (up from 32 million in 2022), continuing at a steady rate of growth through to 2030 with a noteworthy CAGR of 6.1%.

GlobalData's analysis of the US market for minimally invasive neurosurgical devices from 2015 to 2030 suggests that the incidence of strokes and brain arteriovenous malformation (AVM) will increase due to population trends, including a demographic shift towards an aging population, as well as advances in diagnostic techniques. It further predicts that developing countries will experience a slightly faster increase as their healthcare infrastructure improves and more people have access to diagnostic facilities and specialists.

"There is a global shift toward minimally invasive procedures over open craniotomy surgery, as study results continue to show better patient outcomes," Hicks notes. "While minimally invasive surgery is currently not established as the standard treatment for intracerebral hemorrhage (ICH), as clinical trial results are released confirming the benefits of minimally invasive neurosurgery, GlobalData predicts that the usage of this treatment will become more standard, as more guidelines are built and more specialists become comfortable with the technique."

CWT: a partner in precision

Developers of medical devices must work closely with the manufacturers of wire components if they are to continue making smaller and more precise wires to achieve desired clinical outcomes. CWT is a prime example of how this collaborative process pushes back the boundaries of what is possible.

CWT specializes in OD profile grinding (used to shape the external surface of a wire) and centerless grinding (where the wire is shaped between two grinding wheels). It also provides additional services for products like guidewires, K-Wires, orthopedic pins, needle prototypes, ground hypotubes, mandrels, and additional medical related products.

"Wire grinding dates back decades and CWT has only been engaged in this manufacturing technique since 2013," says Boldig. "However, the methods and techniques to grind remain the same. We have not been around for as long as other grinding companies, but if we had to identify one aspect of the equipment that may have revolutionized grinding equipment it would be the computer. Without the advent of the CNC aspect of the machines the setup time would be significantly longer than it currently is."

"Current machine manufacturers are pushing the envelope to make the machines capable of more than what they could in the past," he adds. "As technology continues to advance, the controls of the machines and precision they are built to, will keep up with the drive to make parts smaller."

It is the specialist capability of companies such as CWT, and their willingness to collaborate on innovation to reduce scale, that is driving the outsourced model for medical wire production.

"This is generally an outsourced service due to the cost of the equipment and the knowledge required to operate successfully," Boldig states. "The cost of the equipment could exceed the budget of a project. Companies are forced to explore suppliers who possess this capability. However, there is a difference between a general grinding shop and a medical device contract manufacturer. The latter, as in CWT's case, has the experience and knowledge to set up and run machines capable of achieving the size of finished devices. There are a limited number of machines in the world able to grind a wire down to a 0.025mm diameter. The training required to become proficient in set-up and operation can take up to a year."

"We currently have ten machines supporting our grinding department," he adds. "Two of them are for deburring ground wires and two are for inspection. The six other machines are the workhorses which offer centerless and profile grinding. Our evolution has been the continuous investment into experimentation and understanding the limits of the machines. We continue to push the envelope as to how small these machines will accurately go."

CWT routinely grinds diameters to less than 0.05mm, and can produce profile grinds on solid wire or hypotubes, core wires, mandrels, orthopedic pins and wires, and needle prototypes. It frequently uses stainless steel and nitinol, but it is also experienced in using cobalt chrome alloys and unique materials like magnesium to create components for the medical industry.

CWT offers two types of grinding:

1) Centerless Grinding

Centerless grinding secures the piece between two rotary grinding wheels, and the speed with which each wheel rotates relative to the other is adjusted to change how the material is shaped. Centerless grinders are fast-loading and can run without interruption, have a long operational life, require no resetting, and can accommodate heavier passes than profile grinding.

Centerless grinding is frequently used to create core wires, mandrels and guidewires. The centerless grind taper allows surgical wires to have optimal levels of stiffness and flexibility throughout the length of the medical device. CWT grinds long tapers, short tapers and steps to suit various medical device needs. Furthermore, it can create tapers at any angle and hold very tight tolerances across the profile.

"Centerless is often used for long tapers for core wires where a diameter tolerance is critical," says Boldig. "This method is also suited for long production runs where throughput is essential. This type of grinding can achieve diameters of 0.05mm OD or smaller. Centerless grinding is used for specific applications when the wire diameter is smaller than 1.0mm, and is often used to create wire profiles used in guidewires and small mandrels."

2) OD Grinding

Unlike centerless grinding, OD grinding uses a spindle or fixture to secure the material that is being ground. This type of grinding is preferred for threads, points and specialized profiles in a wire. For example, flat wires for medical components are ground this way. Other shapes include grooves, notches, steps, bumps, and flats.

When a component has a very complex geometry, it may not lend itself to centerless grinding, so profile grinding - the precision grinding of the outside diameter (OD) of cylindrical parts - can be especially useful for parts with features such as grooves, radii and tapers. In some cases, manufacturers can use form grinding, in which the component's profile is formed into the grinding wheel, and this also works well for threads, points and specialized profiles in a wire.

"OD grinding is the technique where we can create different shapes on the outside diameter of a wire," says Boldig. "It is a slower process than centerless, but capable of creating different parts. OD grinding is generally used for wire diameters above 1.0mm, and for pins and larger mandrels."

At CWT, centerless and profile grinding techniques are performed using a fleet of six CNC grinders, each having the capability to produce both techniques.

Grinding applications:

Core Wire Grinding
CWT's core wire grinding process is unique in its ability to centerless grind long lengths of wires at very tight tolerances. It is used for custom guidewire development, prototyping and assembly; custom grind profiles, lengths and diameters; paddles; flattening; and stamping on tapers of varying lengths and diameters for flexibility.

Mandrel Grinding
CWT can manufacture custom mandrels for many applications such as wire coiling and catheter manufacturing. Mandrels can possess many different shapes from many different materials, featuring shapes such as flats, steps, tapers, radii, and angles. These shapes can be ground into stainless steel or nitinol, making grinding a very economical choice for mandrel manufacturing. This process offers tight tolerances and smooth surface finishes.

Frequently, customized medical devices can require customized mandrels for catheter development. Mandrels often address very specific needs, such as tapers or steps, and can be ground with multiple taper levels and very tight tolerances.

Hypotube Grinding
CWT is able to grind hypotubes - long metal tubes with micro-engineered features along their length, frequently used in catheters - to very tight tolerances and very thin wall thicknesses. These grind profiles can include steps, tapers, bevels, and lancet tips.

The company has a strong track record both in prototyping small lots and high-volume production.

Orthopedic Wires
Due to its ability to grind various geometries, CWT can manufacture a range of orthopedic wires including kirschner wires or K-wires (stiff, straight wires sometimes used to repair fractures), Steinmann pins (used for skeletal traction of fractures of long bones), and fixation devices.

Such wires can be complex in their design and require very individualized manufacturing processes. Kirschner wires (k-wires) and Steinmann pins, frequently used as components or fasteners for hand and foot surgery, hold a patient's bones together, so must be both precise and robust in their design and tolerance. Micro-grinding is the only way to obtain that level of precision.

Nitinol Grinding
Nitinol grinding is a technique that few companies can offer. Nitinol (nickel titanium) is highly abrasive and generates a significant amount of heat during the grinding process and thus requires specialized wheels and coolant. CWT has extensive experience with nitinol, with which it can manufacture core wires, mandrels, orthopedic wires, and many other parts.

"Material choice has a significant impact on the grinding process," says Boldig. "Each material has different set-up characteristics than the next. Even within a material family, process parameters may be different from one another. Nitinol requires different set-up characteristics than stainless steel. Nitinol can usually rotate at a faster rate than stainless steel with no degradation in the grind quality."

Conclusion

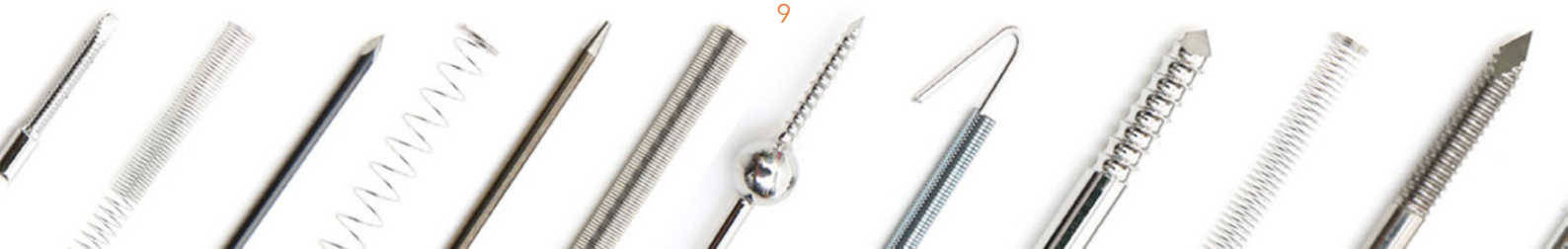
CWT is a small, family-owned business that prides itself on action and service, and which strives to provide a level of customer-focused service that helps it to stand out from its competitors.

"The quality of our products is a main component of this service," Boldig explains. "We are constantly monitoring our processes in real-time to keep every specification in line with our customer's expectations. To provide a superior level of customer service, we use our small size to our advantage. When a customer needs something quick, we can shift our focus in a matter of minutes. This is not something our larger competitors can offer. Our nimbleness and attention to detail elevate CWT to a level above."

Such flexibility is critical as the expanding market for minimally invasive surgery puts ever-greater demands on developers of medical devices.

Recognizing the challenges its customers face going forward, CWT is constantly looking at ways to improve its offering. The next logical step is thru-feed grinding, which will be essential for the high-volume production of mandrels and to support coiling production.

Any device manufacturer will want its partners to keep pace with the development of the market and to produce smaller, more robust and more adaptable wires. That is precisely what CWT aims to do.



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