A NEW PARADIGM

Controlling performance of endodontic files

smarteralloys™

paradigm™

Consistency, safety and cutting efficiency. Together, these attributes define the performance of a file system and culminate in confidence. Confidence instrumenting the root canal leads to better outcomes for the patient and clinician, alike. Confidence allows for better shapes and faster procedures. Confidence relieves tension and allows for focus on what matters. Confidence comes from trusting in the performance of the file system.

Ultimately, there are many factors that influence the performance of a Nickel-Titanium endofile system. These factors can be categorized into geometry and material. Geometrical characteristics include the taper, cutting edges and cross-section. Material characteristics include the transformation temperature range (TTR) of the alloy and the thermomechanical processing of the file.

Materials technology in endodontics has come a long way over the years, allowing for better performance. However, the heat treatments that have been used to achieve these results always come with a compromise. They can be used to control the stiffness of the material, but they affect the stiffness of the entire file. Heat treatments increase flexibility and fatigue resistance, but they soften the cutting edges and decrease the strength of the file.

Ideally, the core of the file is treated to increase the flexibility, while the outer edges remain hard to retain cutting efficiency and resistance to unwinding. This represents a solution outside of the compromise and redefines what is possible. This is now achievable using an entirely new technique: laser processing. Laser processing has a similar effect to heat treatment but is locally controlled to an amazing degree. Now the core of the file can be treated to increase flexibility without affecting the hard cutting edges.

Enter Paradigm, the only laser processed files. Ever. No more compromise. Not flexibility *or* strength. Both. Not fatigue resistance *or* cutting. Both. Now, your rotary or reciprocating file system can give you the consistency that comes with flexibility, the safety that comes with strength, and the efficiency that comes with hardness. Ultimately, the new Paradigm system of files catalyzes confidence by eliminating compromise.

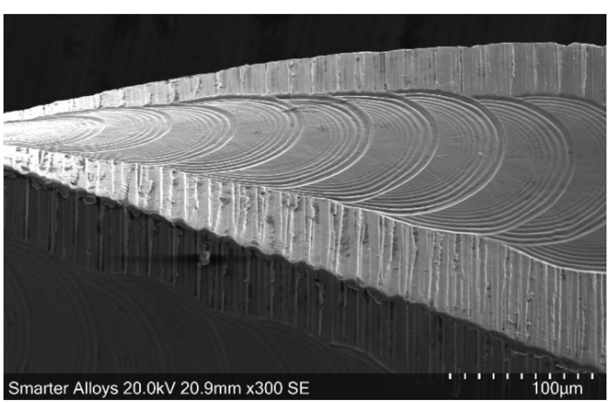

Figure 1 - Laser Processing of an Endodontic File

The difference

Paradigm represents a novel and unique technological approach. The first rotary Nickel-Titanium instrument was reported by Walia, Brantley and Gerstein in 1988 and became commercially available four years later. By 2007, heat-treated Nickel-Titanium instruments were available with improved flexibility and endurance, soon becoming the "gold" standard. Over the last 30 years, advancements in manufacturing processes and design have improved the performance of endodontic files to great heights. This new technology now pushes the limits of materials science and manufacturing technology. Using a laser, the material properties of Paradigm endodontic instruments are tailored with micrometer resolution. This specialized process is both more effective and more accurate than a conventional heat-treatment.

A new material technology in endodontics

Paradigm instruments are based on the same alloys used for modern endodontic instruments. Generally, the difference between popular Nickel-Titanium file systems is the thermomechanical treatment applied to the material. Paradigm adds an extra level of control. The laser processing and thermomechanical treatment work together to achieve the desired performance over every millimeter of the file length.

A heat-treatment affects the entire blade of the instrument. Heat-treatments have been shown to be effective at increasing both flexibility and fatigue resistance of the endodontic file. Torsional strength and cutting efficiency are the trade-offs that typically present as side effects of the process. Increasing flexibility softens the material and reduces the ultimate strength before separation. This is the compromise that comes with a heat-treated file.

The laser process used on Paradigm can be applied to any spot on the blade of the file. It works by changing the alloying composition which, in turn, changes the flexibility at that point. There is a second layer of control afforded by laser processing. The process itself can be tuned to achieve the desired flexibility in any segment of the instrument, along the length *and* the cross-section. The process is applied to the core of the file to achieve increased flexibility of the file along its length. This does not affect the peripheral where torsional strength is provided and where higher hardness is desired to keep the file sharp.

Another layer of control

The degree of flexibility control from the laser process is surprising. Dramatic changes in mechanical properties occur over the span of micrometers. Additionally, the accuracy of the process is extremely high. This is the sophistication that allows the file to perform so well. The laser can be extremely precise in processing a file to affect a flute without influence on the cutting edges, even near the tip, where the space between cutting edges is microscopic.

The laser can affect different sections of the file along its length to achieve the level of flexibility needed for each section of the canal. For example, the tip of the file has the highest flexibility to lead the way down the glide path, navigating tight curves all the way to the apex. To achieve the same effective flexibility without laser processing requires removing material from the file. In other words, a compromise must be made between shaping, navigating the canal, and the risk of separation or unwinding. There are no such compromises with Paradigm.

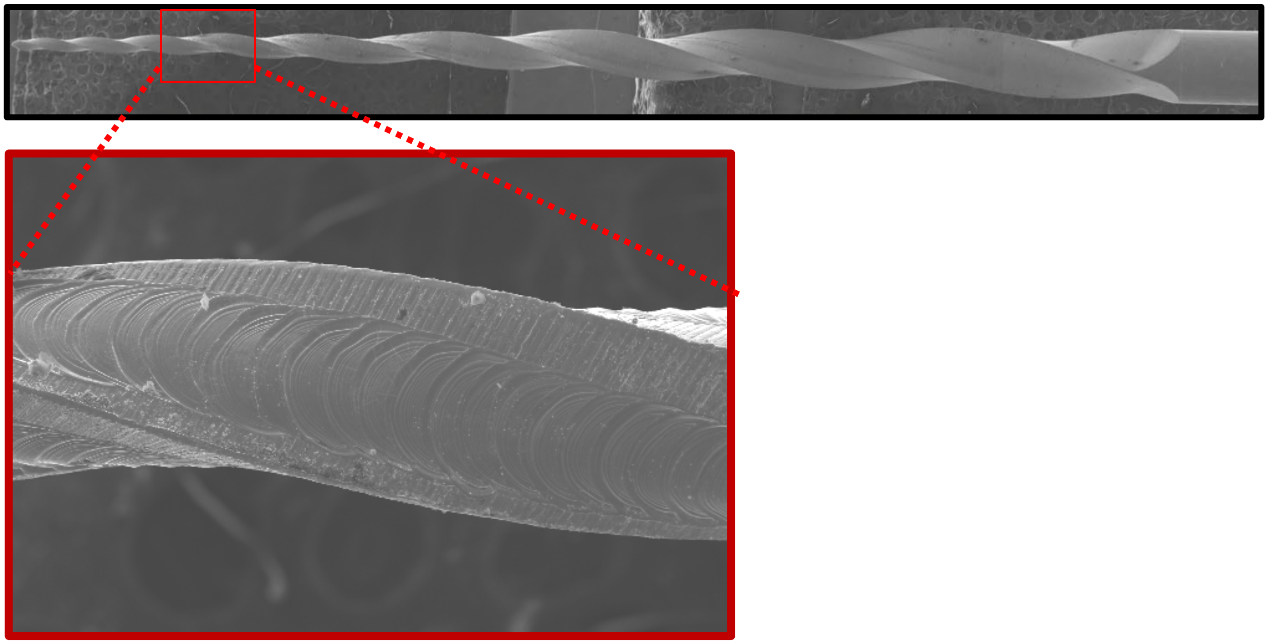

Figure 2 – Laser Processing affects only the flutes of the file

Tailored flexibility

The flexibility of a file is measured by its resistance to bending under controlled conditions. The benchtop test is a good predictor of the clinical feel of the file, indicating how easily the file will be able to navigate a canal. In these tests, the area of interest is near the tip, as this has the highest requirement for flexibility. The coronal section of the file is processed to a lesser degree, allowing energy to be efficiently transmitted down the file to increase torsional strength and cutting efficiency. Laser processing a file increases its flexibility by 25% or more depending on the geometry of the file. The advantages here are obvious, but also insufficiently captured. The increased flexibility has come at very little cost to the torsional resistance and cutting efficiency. The Paradigm files are modified with a tailored proprietary stiffness profile to provide a balanced optimization.

Figure 3 – Flexibility Testing of Endofiles

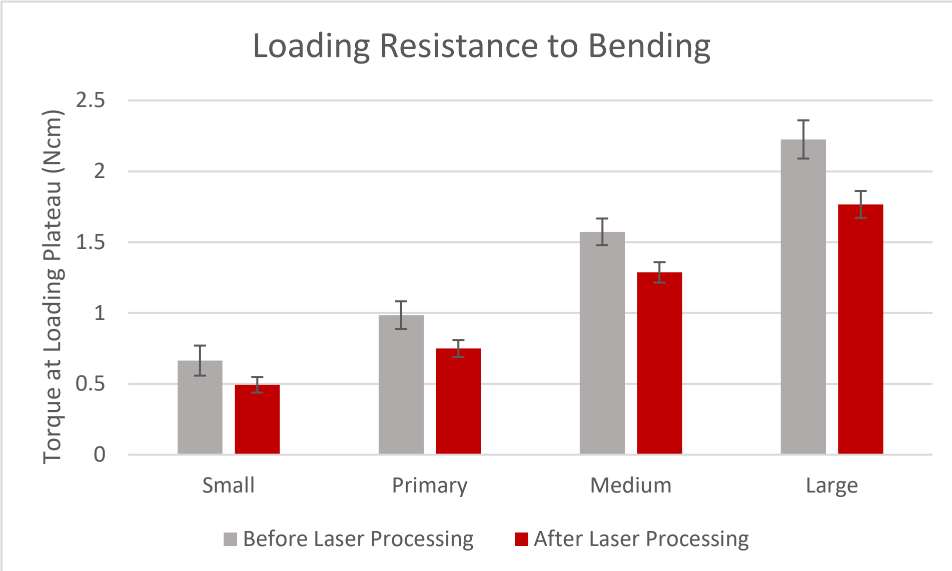

Figure 4 – Flexibility of Files Before and After Laser Processing

Lasting durability

For over a decade, the trend has been to increase flexibility and fatigue response of instruments using a heat-treatment. The outcome is a file that lasts long in laboratory fatigue testing and is not expected to fail in bending fatigue under normal clinical usage. However, the main cause of fracture in instruments is not exclusively due to bending fatigue. Instead, these softer files undergo torsional strain in the canal under repeated cycling, leading to separation. This problem is exacerbated with single file systems that spend more time in the canal, putting increased demands on the instrument. This means the file is subjected to greater cumulative torsional loading. To optimize a file for safety, a balance needs to be made between bending fatigue and torsional strain loading scenarios. With laser processing, the flexibility can be enhanced without making the file too soft. In this way, the file is strong enough to withstand the torsional stress, and soft enough to be resilient.

Uncompromising hardness

NiTi is a special material. The stiffness and hardness of the material changes depending on the transformation temperature range (TTR). Laser processing works to control the TTR in just the area that the laser affects. This means that flutes of the file can be manipulated to soften the file, but the edges of the file are unaffected. Figure 5 shows a cross section of a file at D5 with the areas of laser interaction highlighted in color. The peripheral edges are not touched by the laser. However, the core of the file is modified by the laser process, causing a change in the microstructure of the material. Laser processing can penetrate deep below the surface of the file, targeting a large volume of material for change. The hardness in the unaffected area is up to 31% higher than in the processed areas (shown in Figure 6).

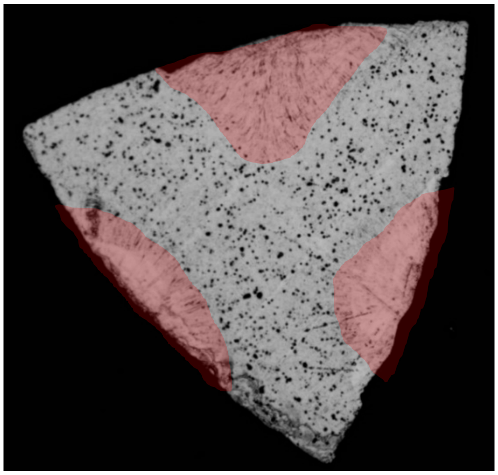

Figure 5 - Cross Section of a File Showing the Possible Depths of Laser Processing

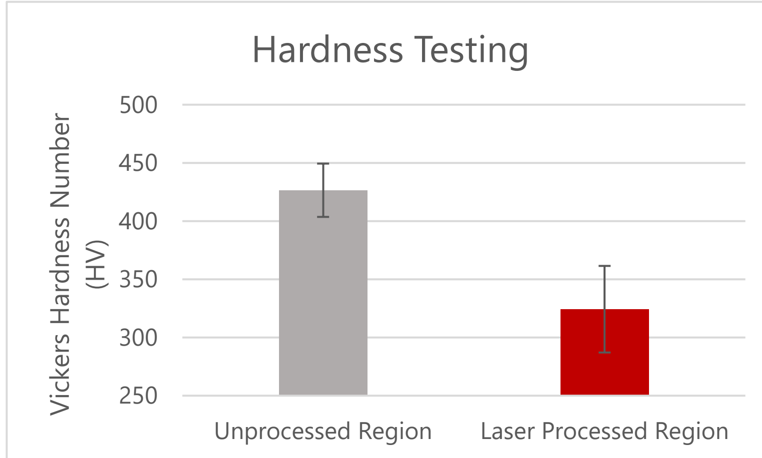

Figure 6 - Hardness Difference of the Laser Processed and Unprocessed Regions of a File

A complete system

Paradigm is available in a rotary and reciprocating system. Paradigm BX rotary is the original laser processed endodontic file system. It is recommended for a progressive procedure and can be used as a replacement to ProTaper Gold™. The consistent geometry results in a familiar canal shape, so obturation is unchanged.

Paradigm Quantum is a reciprocating file system. It is intended for a single file procedure, just like WaveOne Gold™. The workflow for the Quantum system is the same as the WaveOne Gold™.

Table 1 | System characteristics

File System	Technique	Use	Tip Size	Size
paradigm BX™	Rotary	Progression	018	AX (Yellow)
			017	A1 (Magenta)
			018	A2 (White)
			020	M1 (Yellow)
			025	M2 (Red)
			030	M3 (Blue)
			040	M4 (Black)
			050	M5 (White)
paradigm QUANTUM™	Reciprocating	Single File	020	Small (Yellow)
			025	Primary (Red)
			035	Medium (Green)
			045	Large (White)

Clinical outcomes

Benchtop testing demonstrating improved performance is desirable, but truly optimized clinical outcomes is critical. This is where the Paradigm BX and Quantum shine. No benchtop test can truly replicate the conditions of clinical use. It has been seen under clinical use that laser processed files can achieve the flexibility needed to navigate tortuous canals, but still have the cutting efficiency to show a noticeable difference in performance. What is important to the clinician, however, is how the laser processed files *feel*. This is what truly matters, the feeling of a file that expertly navigates the canal, the feeling of a file that cuts efficiently. The feeling of confidence instead of uncertainty during an endodontic procedure. The feeling that creates smooth flowing shapes in every procedure.

The following images represent cases prepared using the Paradigm Quantum reciprocating file. During this procedure, clinician Dr. Owais Sultan, has presented his feedback below. Dr. Sultan is an established Dentist in the Indiana, USA, area. He has been practicing dentistry for 8 years and has been performing endodontic procedures for the same period. He has experience with a variety of endodontic file systems, including ProTaper Gold and WaveOne Gold.

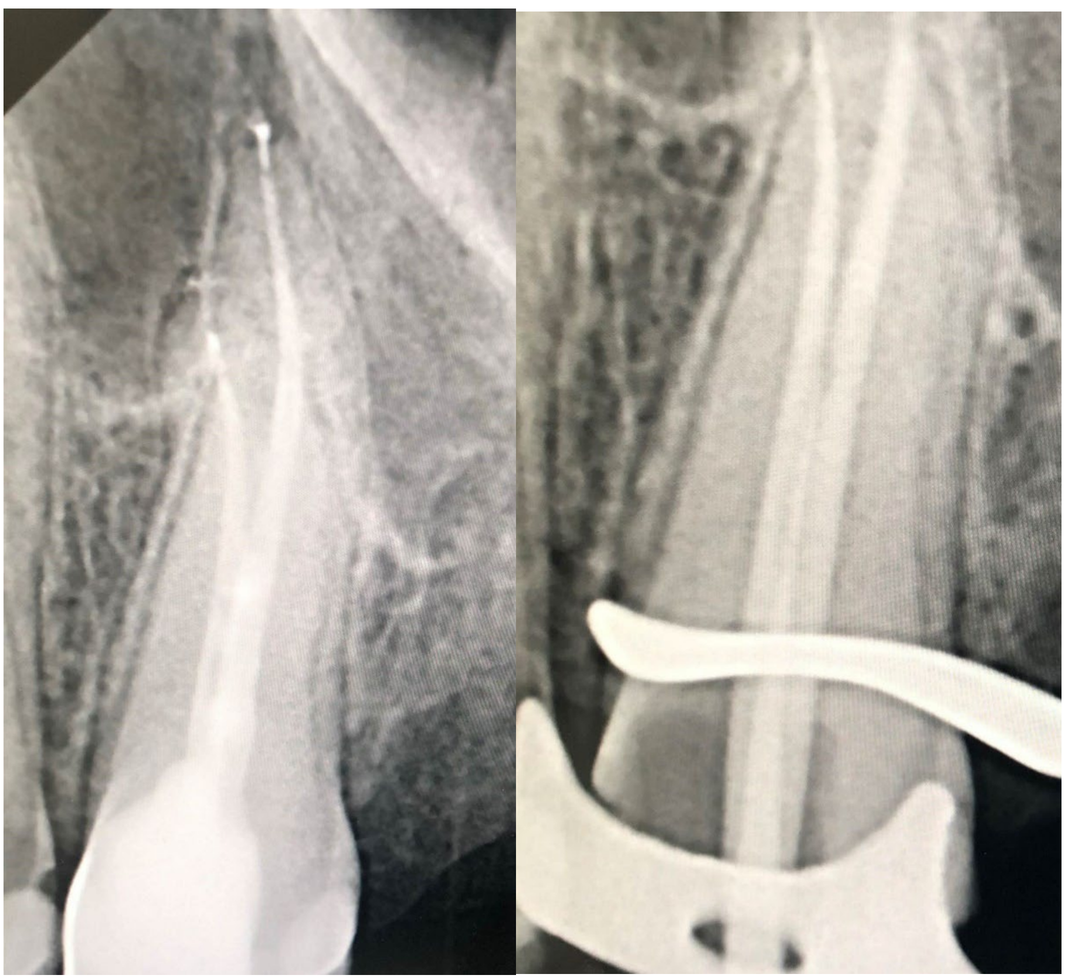

Figure 6 – Paradigm Endofiles create smooth, flowing shapes, making obturation easy

“Initially, the file feels as though it has integrity and structure that allows it to bend easily without fear of separation. I was comfortable with the file right from the beginning. Procedurally, the file looks and works like WaveOne Gold™, and so the transition was seamless, giving me a great deal of confidence. Even though I did not use a glide path file, there was never a point in the procedure that I felt like the file was getting locked-in. The file debrided the canal thoroughly, and I never felt as though there was any danger of damaging the structure of the tooth. The shapes I was able to create were smooth and flowing. Even compared to other leading file systems that I’ve used, this file performed significantly better, with better shapes, and better outcomes.”

- Dr. Owais Sultan

Conclusions

Paradigm BX and Paradigm Quantum are the most technologically advanced file systems ever. Laser processing has a dramatic effect on the performance of the file, improving the flexibility without compromising strength and cutting. This effect is not limited to the benchtop, but it makes meaningful changes to the clinical procedure as well. This improves outcomes, increasing confidence, comfort, and patient care.