medical device technology

Novel Alloy for Speciality Needle Applications

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A novel cobalt-chromium (CoCr) based alloy, optimised for speciality needle applications, has been benchmarked against Type 304 stainless steel in a series of mechanical test and experimental needle trials. The results reported indicate that the CoCr alloy has the potential to overcome current limitations in endoscopic and minimally invasive surgery.

Advancing the art

Endoscopic or minimally invasive surgery involves entire medical procedures being performed from outside the patient's body. Because surgical devices are manipulated remotely without direct contact with, or vision of, the diseased tissue or operative site, the surgery is often constrained by physical, visual, spatial and haptic constraints.[1–8] Given the phenomenal worldwide success of minimally invasive surgery during the past decade, treatments are continuously advancing and placing greater demands on the surgical devices employed.

Traditionally, Type 304 stainless steel (SS 304) has been the material of choice for endoscopic or minimally invasive devices. The well balanced microstructure of SS 304 allows it to be severely drawn and formed into long fine tubes. In addition, the alloy has good machinability and weldability and is widely available and cost efficient. Although SS 304 is versatile, its mechanical properties are imposing design limitations on surgical devices, which restrict more complex advanced surgical procedures. To meet growing demands for greater pushability and kink resistance, endoscopic shape set resilience and hardness, a cobalt-chromium (CoCr) alloy has been optimised. The mechanical properties of the alloy have been evaluated and benchmarked against SS 304 and the results are reported here.

Test methods

Needle tubes of 19 and 22 gauge (Table I shows nominal dimensions) made from SS 304 and from the novel CoCr alloy were subjected to a series of mechanical tests. Tensile testing was performed using a 2.5 kN load cell, a test speed of 25 mm/min, a grip to grip separation of 76 mm together with a preload of 5 N. Elongation was measured over a 50 mm gauge length using high resolution macro-extensometers. To compare how the tubes would perform during surgical and endoscopic application, they were subjected to column strength testing, three point bend testing, endoscopic shape set testing, package shape set testing and hardness testing.

Column strength/compression testing was performed to measure pushability and kink resistance. The test involves axial loading a tube in compression until it kinks (Figure 1). Force was measured with a 200 N load cell and displacement by crosshead travel. A 90 mm gauge length and a test speed of 50 mm/min were used. Column strength was identified by critical buckling force, and crosshead displacement to kink point was captured to measure kink resistance.

Tube flexibility was measured using three point bend testing that involves the flexural loading of a specimen to a predefined

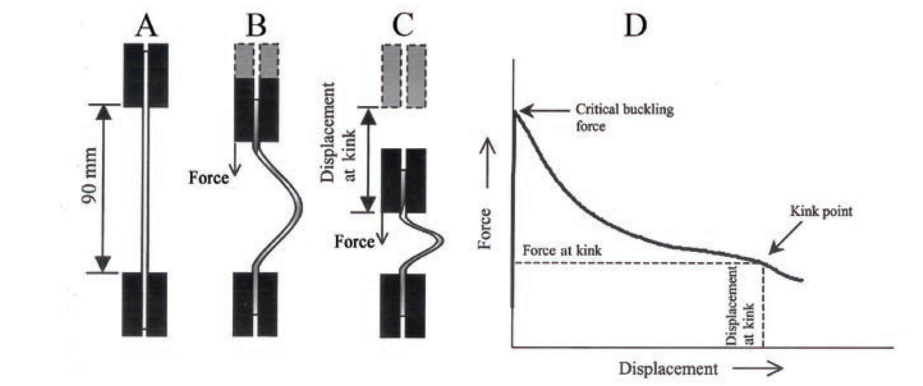
Table I: Nominal needle gauge dimensions.

Needle gauge	Outer diameter	Inner diameter	Wall thickness
19 gauge	1.067 mm (0.042 in.)	0.876 mm (0.0345 in.)	0.0965 mm (0.0038 in.)
22 gauge	0.719 mm (0.0283 in.)	0.592 mm (0.0233 in.)	0.076 mm (0.003 in.)

Table II: Average tensile results showing ultimate tensile strength (UTS), yield strength (yield) and elongation; average column strength results are also presented. Sample size, n = 10.

		UTS kpsi	Yield kpsi	Elongation (%)	Column Strength (N)	Displacement at kink (mm)
22 gauge	CoCr	241	194	6.3	8.7	44.3
	SS 304	223	172	4.4	6.6	41.4
19 gauge	CoCr	236	191	7.9	32.2	16.6
	SS 304	206	161	5.3	24.1	17.5

Figure 1: Schematic of column strength test. (A) shows a specimen clamped ready for testing; (B) the tube is loaded in compression and buckling has occurred; (C) the tube has kinked and one wall has collapsed on the other; (D) is a plot of force measured by the load cell versus the displacement measured by the machine crosshead.



deflection. The force was measured with a 200 N load cell with displacement measured by crosshead travel. The major span was set at 15 mm with test speed set at 1 mm/min. Using a preload of 1 N, force was measured at 0.5 mm displacement.

Endoscopic shape set testing reflects the ability of the alloy to resist permanent deformation when deployed through a torturous path; hardness reflects resistance to localised deformation or blunting during deployment. For endoscopic shape set testing, a needle was advanced through an endoscope to the exit point. A 90° bend was then applied on the end of the scope before the needle was further advanced to a distance of 150 mm from the exit point (Figure 2). The needle was completely withdrawn from the endoscope and evaluated for permanent deformation.

For hardness testing, cross-sections of five needles of each material were mounted in resin, wet ground and polished with a 3 micron diamond solution. Hardness was measured using Vickers method with an applied load of 0.1 kg.

To investigate whether the needles would take any shape while in storage, package shape set testing was performed. One metre long needle sections were placed in 152.4 mm diameter coils that are common for catheter packaging. After 24 h the needles were removed and placed onto a flat table. The maximum distance of deflection or curvature from the straight edge (package set value, l) was measured using a ruler as shown schematically in Figure 3. The needle was dropped on a flat table three times and an average value from the three measurements recorded.

Figure 2: Endoscopic shape set resilience test jig.

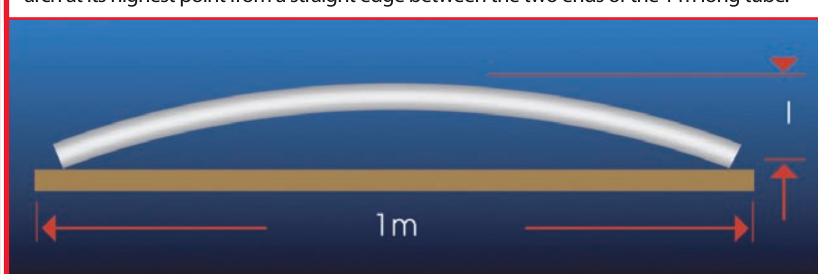
Surgical handling

Column and tensile results are presented in Table II. In both sizes, the CoCr alloy gives higher tensile strength (8–14%), yield strength (12–18%) and elongation (43–49%). Figure 4 presents a typical column strength curve from each alloy for the 22 gauge needle size. The CoCr alloy is superior in column strength (pushability) and kink resistance. Comparing the column strength results in Table II, the force required to initiate buckling for 22 and 19 gauge CoCr alloy is 31% and 34% greater, respectively, than that required for SS 304. Therefore, it can be concluded that more force can be applied to the novel alloy to overcome resistance during navigation of a tortuous path. The kink performances of both materials are similar for each of the needle sizes. Comparing results from three point bend testing (Table III), the CoCr alloy exhibits 25–27% higher stiffness than those exhibited by SS 304 for the 19 and the 22 gauge needles. These latter results reflect the column strength results that show the CoCr alloy is less likely to buckle during deployment, thereby giving greater pushability.

Endoscopic performance

Endoscopic shape set testing revealed that the CoCr needles undergo less permanent deformation during deployment through an endoscope. In Figure 5 (top), it can be observed that the CoCr needle protrudes in a straight path from the endoscope exit point whereas the SS 304 needles protrude in a curved fashion. After the needles have been withdrawn from the endoscope, it is clearly seen that there is substantially less permanent deformation on the CoCr needle than on the SS 304 needle (bottom of Figure 5). When the needles were deployed through an endoscope and advanced with the aim

Figure 3: Schematic of a specimen after package set resilience test. "l" is a measure of the arch at its highest point from a straight edge between the two ends of the 1 m long tube.



of penetrating a membrane (Figure 6), it was found that the SS 304 needle bends further on meeting resistance from the membrane so that penetration was not achieved. In contrast, the CoCr needle penetrated the membrane without difficulty. The failure of the SS 304 needle was attributed to the curvature/ shape set taken by the needle during advancement through the endoscope and also its lower pushability.

During hardness testing, the CoCr alloy recorded an average value of 520 Vickers and SS 304 recorded 421 Vickers. These results suggest that the CoCr alloy is approximately 24% harder than SS 304, which indicates that CoCr needles are more resistant to blunting and more likely to retain their sharpness during repeated deployment.

Packaging and transportation

Results from package shape set testing reflected endoscopic shape set results. The CoCr alloy needles recorded lower "l" values ("l" is maximum distance of deflection as previously depicted in Figure 3) than the SS 304 needles (Figure 7). These results indicate that CoCr needles will be straighter when removed from standard packaging and as a result will be easier to apply and manipulate.

New design possibilities

When comparing proprietary CoCr needles with those fabricated from conventional SS 304 in 19 and 22 gauge sizes, the CoCr alloy was found to present superior needle attributes. From the trials conducted, it can be concluded that the CoCr alloy overcomes current constraints experienced with SS 304 by improving pushability without compromise to kink resistance, sharpness, penetration ability and ease of navigation. These properties will facilitate medical device engineers and designers in tackling more complex challenges previously not possible.

Figure 4: Comparison of two typical column strength curves obtained from 22 gauge needles.

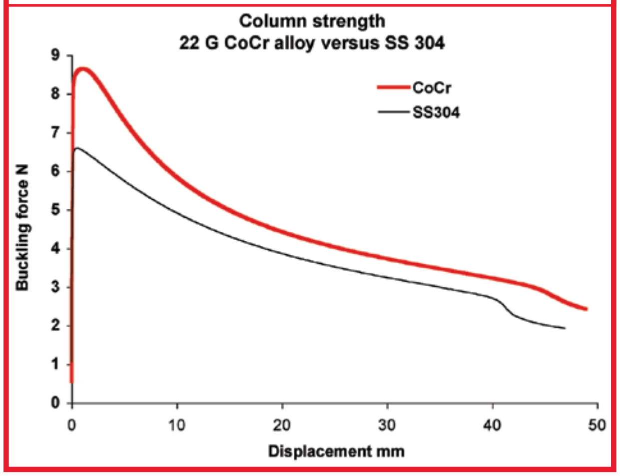


Figure 5: Endoscopic shape set results for 19 gauge needles with the top showing the needles protruding from the endoscope exit point and the bottom showing the needles after they have been removed from the endoscope.

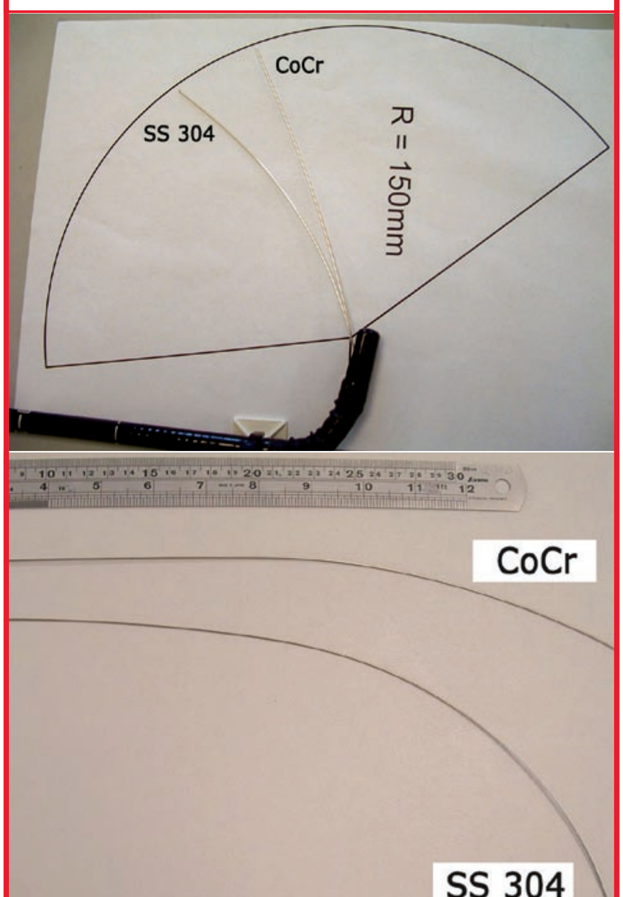


Figure 6: The CoCr needle advances and penetrates the membrane while SS 304 fails to achieve penetration and instead bends further.

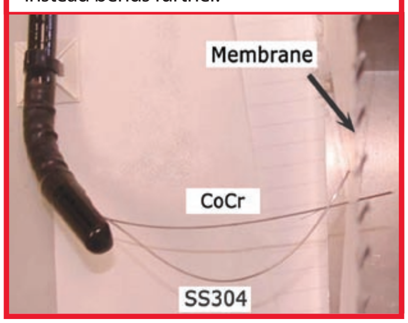
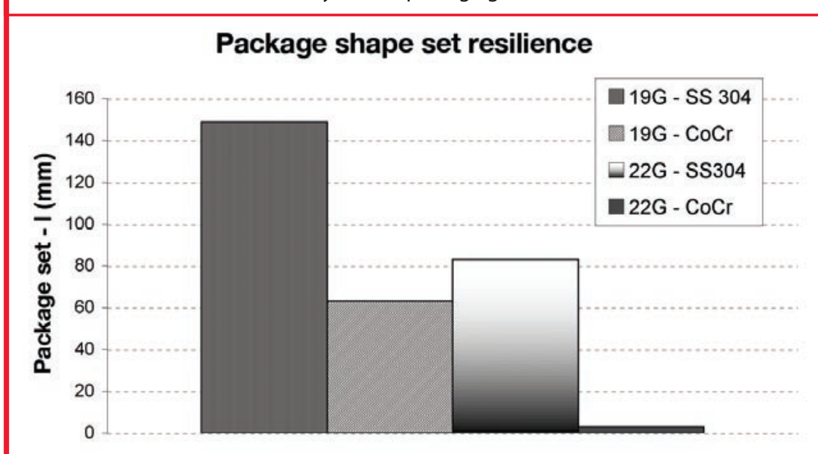


Table III: Average three point bend results. Sample size, n = 5.

		Three point bend force (N)
22 gauge	CoCr	14.4
	SS 304	11.4
19 gauge	CoCr	13.7
	SS 304	10.9

Figure 7: Package set results. "l" values are taken from a measure of the arch at its highest point from a straight edge between the two ends of the 1 m long tube (see Figure 4) after the tube has been stored in a 152.4 mm (6 in.) diameter coil commonly used in packaging.



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