CATHETER AND SPECIALTY NEEDLE ALLOYS

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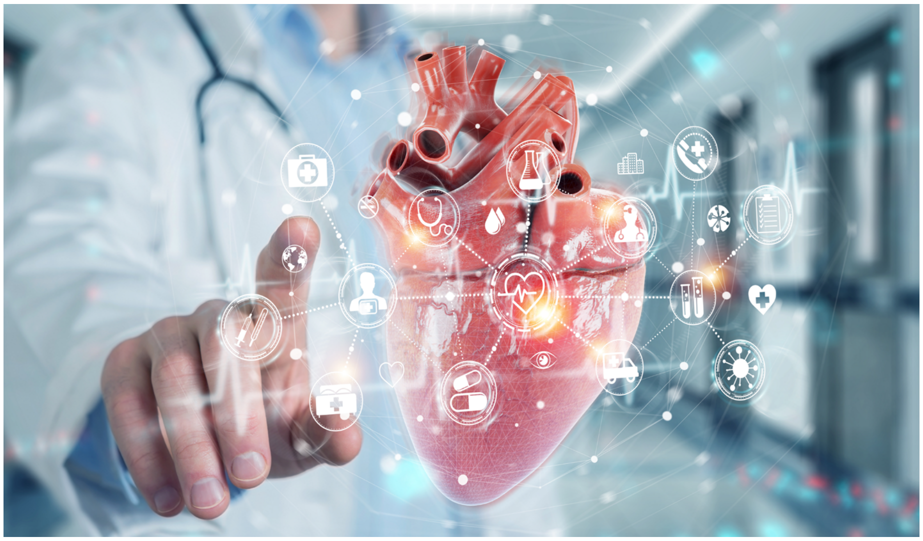


ABSTRACT

A cobalt-chromium alloy, 17-7PH and nanoflex (Sandvik 1RK91) stainless steels were evaluated as possible alternative alloys to 304 stainless steel for minimally invasive and endoscopic surgical tools. From a series of mechanical test and experimental needle trials, the cobalt-chromium alloy was found most superior to 304 stainless steel offering greater tensile properties, column strength / pushability and kin resistance. It also displayed notably less permanent deformation in both endoscopic and package shape set resilience trials. The additional hardness offered by the cobaltchromium provides greater resistance to needle blunting during deployment. Overall, the cobalt-chromium alloy offers possibility for current design limitations due to material choice in both endoscopic and minimally invasive tools to be overcome allowing potential for new surgical advances to be made.

INTRODUCTION

Short patient recovery time along with reduced or no patient scaring has lead to a phenomenal worldwide transition to minimally invasive surgery over the past decade. Both minimally invasive and endoscopic medical procedures induce minimum patient trauma and are carried out entirely from outside the patient's body. In comparison to open surgery, surgical tasks are performed through remote manipulation of tools without direct contact or vision of the diseased tissue or operative site. This in turn leads to additional physical, visual, spatial and haptic constraints for the physician (1-8). Nevertheless, as the adoption and growth continues in these procedures, treatments are continuously advancing with the net result of greater demands being placed on surgical tools.

The material of choice with engineers and designers of endoscopic or minimally invasive tools has traditionally been 304 stainless steel (SS 304). The alloy is widely available, cost efficient and offers a well balanced microstructure that allows it to be severely drawn and formed into long fine tubes that are often called "hypotubes" or "device shafts". SS 304 has good machinability and weldability that allows various further processing steps to be carried out and features to be sometimes added in order to tailor the end performance of the tubes to the specific needs of the device. These long fine hypotubes typically make-up the core of the device and determine its overall mechanical performance.

Although SS 304 is very versatile, its mechanical properties are gradually inducing design limitations on surgical tools required for more complex advanced surgical procedures. To meet growing market demands for an alloy with superior pushability, kink resistance, tensile properties and shape set resilience a cobalt-chromium (CoCr) alloy, nanoflex and SS17-7 precipitation hardenable stainless steels were evaluated and developed as possible alternative alloys. All alloys chosen for evaluation were deemed to have similar or better biocompatibility and corrosion resistance to SS 304 from literature.

MATERIALS & TEST METHODS

Nominal tube dimensions evaluated and potential areas of application are presented in Table 1. Various alterations in the processing were carried out with the aim of maximizing and optimizing the resultant mechanical properties. SS304 was in the as drawn condition, 17-7PH was heat treated using RH950; Nanoflex (Nano-1) was heat treated for 3h @595 ºC with Nano-2 heat treated for 1h @620 ºC. CoCr-1 to CoCr-5 representing five different proprietary processing conditions developed by TE Connectivity.

Column strength / compression testing was carried out to measure pushability and kink resistance of the hypotubes. The test involves axial loading a hypotube in compression until it kinks in a Zwick/Roell universal test machine as describes in previous work (9). Force was measured with a 200 N load cell and displacement by crosshead travel. A gauge length of 90 mm and a test speed of 50 mm/min were used for 23 and 19 gauge hypotubes. A schematic of a resultant force versus

Applications		O.D.	I.D.	W.T.
Minimally Invasive	Specialty needle			
Neuro	29 G	0.323 mm (0.013")	0.187 mm (0.007")	0.068 mm (0.003")
Coronary & Peripheral	23 G	0.635 mm (0.025")	0.475 mm (0.019")	0.080 mm (0.003")
Endoscopic	19 G	1.067 mm (0.042")	0.876 mm (0.034")	0.097 mm (0.004")

Table 1: Nominal hypotube / needle dimensions along with potential areas of application. G is needle gauge, O.D. is outer diameter, I.D. is inner diameter, W.T. is wall thickness.

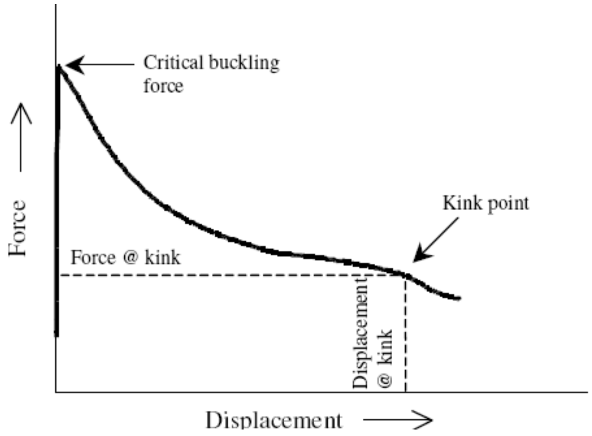


Figure 1: Schematic of a typical column strength test curve highlighting the key features of the curve.

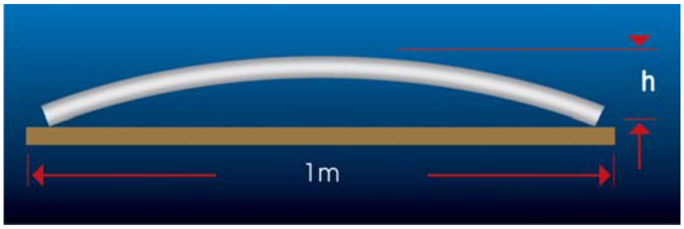


Figure 2: Package set resilience (9).

displacement curve is presented in Figure 1. The critical buckling force is captured to identify column strength / pushability with overall displacement at kink captured to measure and compare kink resistance. After testing, fracture surfaces from each alloy were examined with scanning electron microscopy (SEM) in the secondary electron mode to understand the mode of failure.

For 29 gauge hypotubes, a gauge length of 25 mm and a test speed of 50 mm/min were used. Since no “kink point” or drop in force was observed with these small hypotubes, the “damage tolerance” of the column strength test samples after testing was measured by tensile testing. Testing was carried out using a 2.5 kN load cell, a preloaded of 1N and a test speed of 100 mm/min.

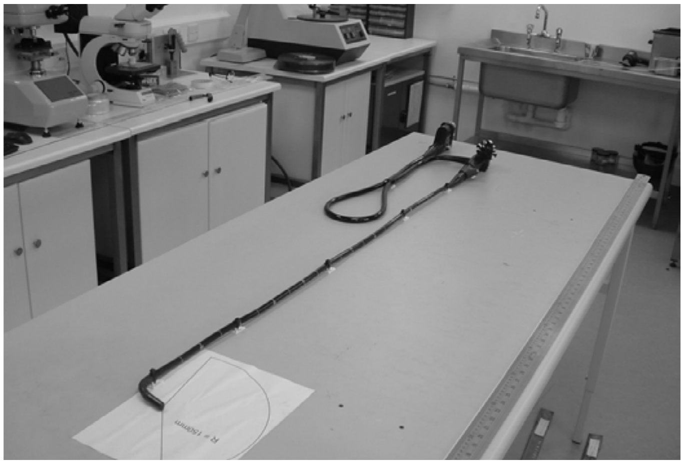


Figure 3: Endoscopic shape set resilience test jig (9).

Normal tensile testing on raw tubes was also carried out using the Zwick/Roell universal test machine fitted with a 2.5 kN load cell along with high resolution macro-extensometers. A grip to grip separation of 76 mm along with a preload of 5N was used while elongation measured over a gauge length of 50mm using the extensometers. Test speeds of 5 mm/min and 25 mm/min were used during testing. Ten tensile samples were tested at each gauge size.

To investigate whether the needles would take shape while in storage due to packaging, package shape set testing was performed. One meter long tube sections were placed in 152 mm (6”) diameter coils that are standard for catheter packaging. After 24 hours the needles were removed from the coil and placed onto a flat table. The maximum deflection from the straight edge (set resilience value, h) as shown in Figure 2 was measured using a ruler. The needle was dropped on a flat table 3 times and an average value from the three trials is recorded. The lower the “h” value, the straighter the hypotube when removed from standard packaging and as a result it will be easier to deploy and manipulate.

Endoscopic shape set testing (Figure 3) was performed on 19 gauge needle sizes that are commonly used in such procedures and reflects the ability of the alloy to resist permanent deformation when deployed through a torturous path. 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 150mm from the exit point. The needle was completely withdrawn from the endoscope and evaluated for permanent deformation.

Material hardness reflects resistance of a needle tip to localized deformation or blunting during deployment. For hardness testing, five hypotube cross-sections from both SS 304 and Co-Cr were mounted in resin, wet ground and polished with 3 μm diamond solution to expose the cross section of the needle. Hardness was measured using an Indentec® Vickers Micro-Hardness tester, with an applied load of 0.1 kg.

Penetration testing was also carried out using the Zwick/Roell universal test machine fitted with a 2.5 kN load cell. 19G needles were advanced using a test speed of 50 mm/min with the aim of penetrating a 3 mm PVC membrane.

RESULTS

Coronary or 23 Gauge Needle Applications:
Column strength test results are summarized in Figure 4. The ideal properties are maximum critical buckling force combined with maximum displacement at kink. The CoCr was the most versatile of the alloys – depending on the processing it could be optimized to give the highest critical buckling force or the greatest displacement at kink. CoCr-2 produced the most optimum properties of all the alloys tested giving a good combination of high critical buckling force combined with good displacement at kink. During testing, some of the SS 17-7PH samples broke in a brittle manner. Figure 5 shows a brittle intergranular fracture surface from SS 17-7PH. The other alloys failed in a ductile manner.

Tensile, column and package shape set resilience results are summarized in Table 2. Of the alloys tested CoCr-2 gave the most constructive blend of mechanical properties. Comparing directly with SS304 and evaluating the percentage increases, the CoCr-2 gave 11% and 13% higher tensile and yield strength respectively along with 72% higher elongation. For force required to initiate buckling, CoCr-2 recorded 16 % greater than that required for SS 304 and it also displayed a 10% increase in kink resistance. For shape set, the lower the "h" values the better the shape set resilience with CoCr-2 completely out-performed SS304 with a reduction of 94 % in "h" value.

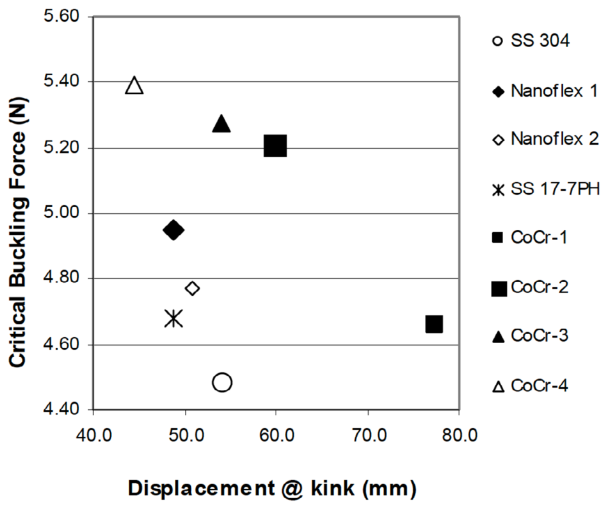


Figure 4: Recorded critical buckling force versus displacement at kink for 23 Gauge needles or Coronary applications, O.D. 0.635 mm, I.D 0.475 mm, (0.025" and 0.019").

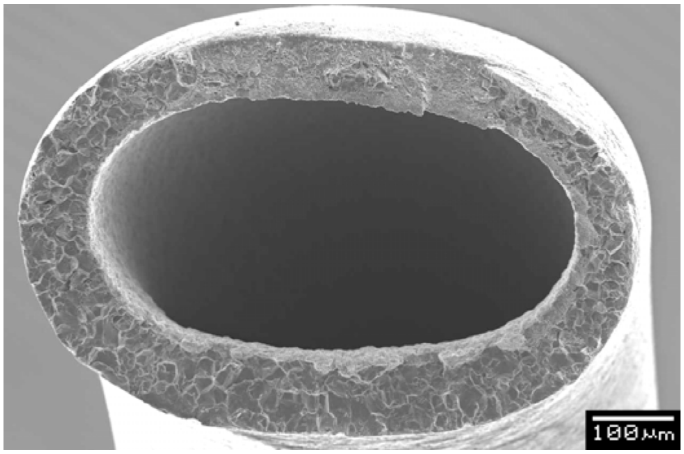


Figure 5: SEM micrograph of a column strength test fracture surface from a SS 17-7PH test sample showing brittle intergranular fracture.

	Column Strength		Tensile			Shape Set
	Fc [N]	Dk [mm]	UTS [ksi]	Yield [ksi]	Elong [%]	h [mm]
304	4.48	54.3	194	150	5.2	72
17-7 PH	4.68	48.8	208	182	8.9	NA
Nano-1	4.95	48.7	257	215	4.6	5
Nano-2	4.77	50.8	217	181	7.9	33
CoCr-1	4.66	77.5	211	139	11.3	86
CoCr-2	5.21	59.8	216	169	8.9	4
CoCr-3	5.28	54.0	220	181	8.0	2
CoCr-4	5.39	44.5	227	200	5.6	2

Table 2: Average tensile results for O.D. 0.635 mm, I.D 0.475 mm, (0.025 and 0.019 inch) showing Ultimate Tensile Strength (UTS), Yield Strength (Yield) and Elongation (Elong). Also presented are average column strength and shape set resilience results. (Sample size, n = 10). NA is not analyzed.

Endoscopic Performance or 19G Needles Applications:
Mechanical results (column, tensile and shape set) for 19G hypotubes are presented in Table 3. The CoCr-5 alloy has 34% greater critical buckling force / pushability than the SS 304 and a marginally lower displacement at kink (16.6 mm versus 17.5 mm for SS304). The tensile properties of the CoCr alloy were also far superior with increases of 15% for UTS, 19% for YS and 49% for Elongation. The same trend of superiority was followed with shape set resilience with a reduction of 58%.

Endoscopic shape set testing of 19G needles show that Co-Cr needles undergo less permanent deformation during deployment through an endoscope. In Figure 6a it can be observed that the Co-Cr needle sizes protrude 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 Co-Cr needle, than on the SS 304 needles (Figure 6b).
These results reflect package shape set testing.

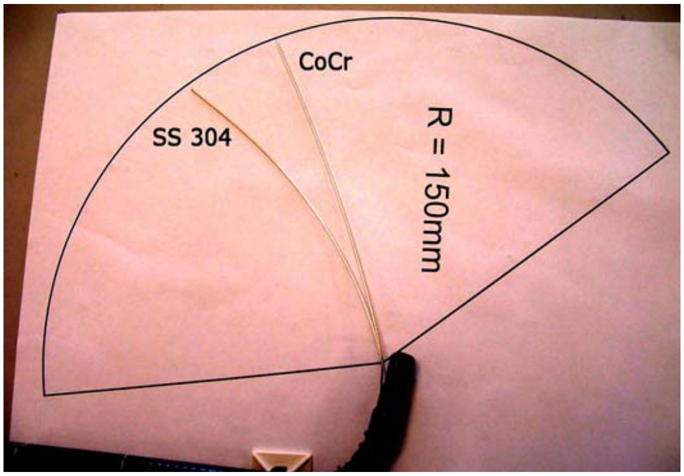
Hardness testing found the CoCr-5 alloy recorded an average value of 520 Vickers with SS 304 recording 421 Vickers. From these results, the CoCr-5 tubes are approximately 24% harder than SS 304 which indicates that CoCr-5 needles are more resistant to blunting and are more likely to retain their sharpness during deployment than SS 304.

Needle penetration testing through a 3 mm PVC membrane (Figure 7) found that SS 304 needles buckled and permanently bent on meeting resistance from the membrane, such that penetration was not achieved. In contrast, the CoCr-5 needle penetrated the membrane without difficulty (Figure 7). The failure of the SS 304 needle was attribute to the lower column strength / pushability and to possibly the lower hardness of the needle.

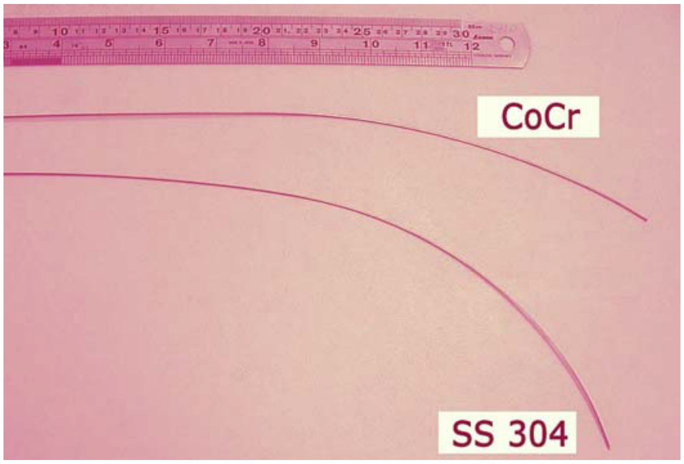
Neuro Applications:
Mechanical results for neurovascular sizes hypotubes (CoCr-2 & SS304) are presented in Table 4. Since the hypotube dimensions were small, no noticeable drop in force at kink point was measured during column strength testing as shown in Figure 8. The "damage tolerance" after column strength testing was evaluated by then tensile loading the samples with a plot of force versus elongation shown in Figure 9. For comparison purposes normal/unloaded samples were also tensile loaded. It is clearly seen that CoCr-2 has much greater "damage tolerance" and requires three times more force than SS304 to cause breakage on samples that have been previously compression loaded. Also the CoCr-2 compression loaded samples retains force similar to the normal/unloaded samples to cause breakage. A summary of mechanical results are presented in Table 4. CoCr-2 again records superior mechanical properties. Critical buckling force increased by 7%, ultimate tensile strength by 2%, yield strength by 2%, elongation by 63% and shape set resilience by 70%.

	Column @ 90mm		Tensile			Shape Set
	Fc [N]	Dk [mm]	UTS [ksi]	Yield [ksi]	Elong [%]	h [mm]
SS304	24.1	17.5	206	161	5.3	149
CoCr-5	32.2	16.6	236	191	7.9	63

Table 3: Average mechanical results from O.D. 1.067 mm, I.D. 0.876 mm (0.042 and 0.034 inch) showing Critical Buckling Force (Fc), Displacement at Kink (Dk), Ultimate Tensile Strength (UTS), Yield Strength (Yield), Elongation (Elong) and Shape Set Resilience (h).



a



b

Figure 6: 19 Gauge endoscopic needles shape set results with a showing the needles protruding from the endoscope exit point and b showing the needles after they have been removed from the endoscope (9).

PENETRATION PROGRESSION

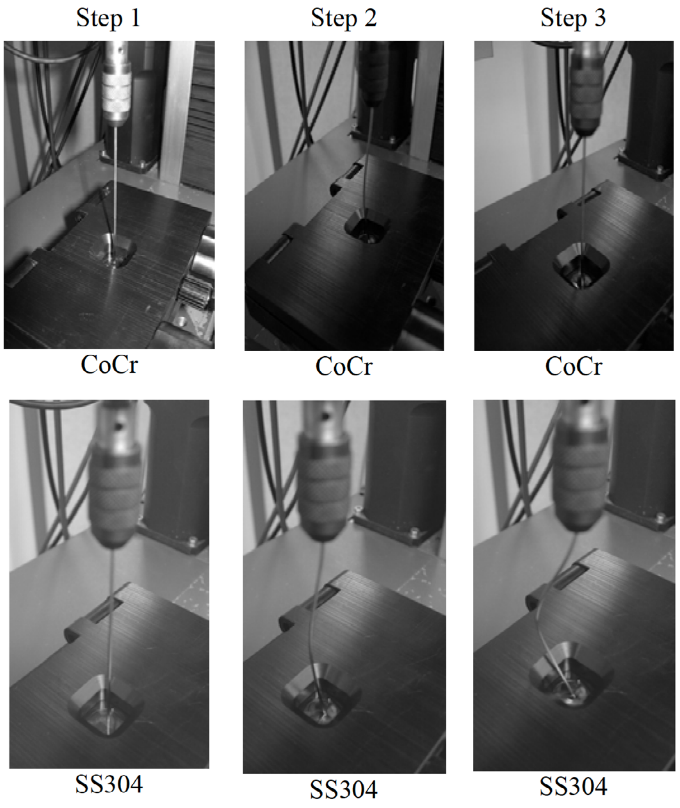


Figure 7: Co-Cr advances and penetrates the membrane while SS 304 fails to achieve penetration and instead bends.

	CS	Damage Tolerance		Tensile			Shape Set
	Fc [N]	Fmax [N]		UTS [ksi]	Yield [ksi]	Elong [%]	h [mm]
		B	A				
SS304	4.72	87	21	241	188	3.3	17
CoCr-5	5.22	95	89	247	192	5.7	5

Table 4: Average tensile results showing Ultimate Tensile Strength (UTS), Yield Strength (Yield) and Elongation (Elong). Also presented are average column strength (Fc) and damage tolerance results – the maximum force (Fmax) recorded during tensile loading before(B) and after(A) compression loading. Sample size, n = 10, O.D. 0.323 mm, I.D. 0.187 mm (0.013 and 0.007 inch)

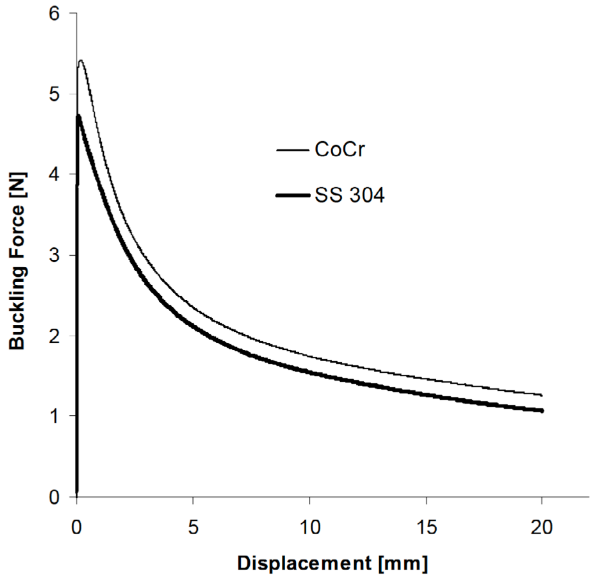


Figure 8: A comparison of two typical column strength curves obtained from O.D. 0.323 mm, I.D. 0.187 mm (0.013 and 0.007 inch) Co-Cr and SS 304.

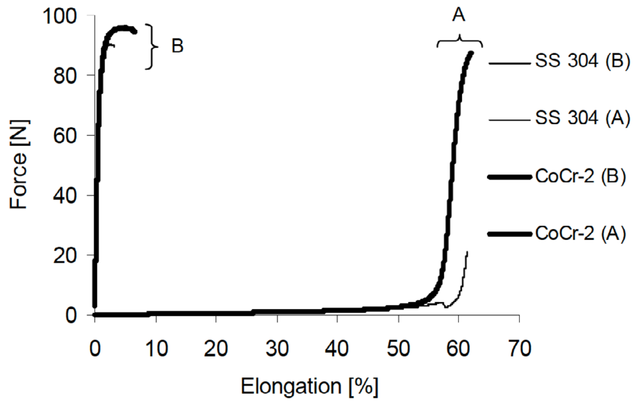


Figure 9: A comparison tensile forces from before (B) and after (A) column strength / compression loading to 20mm displacement over a gauge length of 25mm from O.D. 0.323 mm, I.D. 0.187 mm (0.013 and 0.007 inch).

DISCUSSION

Focusing on applications there are a number of key qualities the CoCr alloy offers above SS304. The increased column strength / pushability can be used to negotiate more torturous paths. Alternatively it could be used to reduce wall thickness while still maintaining mechanical properties similar to SS304 and thus increase the size of the inner diameter allowing increased balloon inflation / deflation speed in comparison to hypotubes of SS 304 with the same outer diameter.

The greater hardness of CoCr provides increased resistance to local deformation and thus gives greater sharpness retention during needle penetration. The increased hardness combined with pushability and possibly larger inner diameter make the CoCr alloy an obvious choice for applications such a biopsy needles. Combining the latter attributes with shape set resilience, endoscopic biopsy needles become obvious applications. These are just few new options that are available to medical device engineers and designers as they advance and tackle complex challenges previously not possible.

CONCLUSIONS

The performance of a CoCr alloy, 17-7 PH and Nanoflex stainless steels were evaluated as possible alternatives to conventional SS 304 for hypotube and needle applications.

SS 17-7PH was found to moderately increase tensile properties and pushability however kink resistance was worse than SS304 with some intergranular brittle fractures experienced during testing. For these latter happenings, SS17-7 was abandoned as an alternative to SS304 for hypotube and needle applications.

Nanoflex offered the best tensile properties of all alloys examined and it also displayed reasonable pushability and very good shape set resilience. Despite these former attributes Nanoflex was discarded for hypotube and needle applications due to worse kink resistance than SS 304.

The CoCr alloy was the most versatile and superior of all alloys examined. Depending on the requirements of the application, it can be tailored to maximize pushability or kink resistance or to provide an optimum of the two. Combining these former characteristics with higher hardness and excellent tensile properties, CoCr delivers superior penetration-ability. It also delivered the best shape set resilience of all alloys tested and was found to have greater damage tolerance than SS304.

From the trials conducted, it can be concluded that the CoCr alloy delivers the sought after properties that are required to tackled more complex medical challenges previously not possible with SS 304.

REFERENCES

1. Vilmann P, Hankcke S, Henriksen FW, Jacodsen GK. Endosonographically-guided fine needle aspiration biopsy of malignant lesions in the upper GI tract. Endoscopy 1993; 25: 523-7.
2. Shin HJ, Lahoti S, Sneige N. Endoscopic ultrasound-guided fine-needle aspiration in 179 cases: the M. D. Anderson Cancer Center experience. Cancer 2002; 96: 174-80.
3. Vilmann P, Hancke S, Henriksen FW, Jacobsen GK. Endoscopic ultrasonography with guided fine needle biopsy of lesions in the upper GI tract. Gastrointest. Endosc. 1995; 41: 230-5
4. Wiersema MJ, Wiersema LM, Khusro Q, Cramer HM, Tao LC. Combined endosonography and fine needle aspiration cytology in the evaluation of gastrointestinal lesions. Gastrointest. Endossc. 1994; 40: 199-206
5. Williams DR, Sahai AV, Aabakken L et al. Endoscopic ultrasound of guided fine needle aspiration biopsy: a large single center experience. Gut 1999; 44: 720-6
6. Giovannini M, Seitz JF, Monges G, Perrier H, Rabia I. Fine-needle aspiration cytology guided by endoscopic ultrasonography: results in 141 patients, Endoscopy 1995; 27: 171-7.
7. Cao CGL, MacKenzie CL, Task and motion analyses in endoscopic surgery, 1996 ASME IMECE Conference Proceedings, 5th Annual Symposium on Haptic Interfaces for virtual environment and teleoperator systems, Atlanta Georgia. P583-590
8. Chang KJ, Katz D, Durbin TE et al. Endoscopic ultrasound-guided fine needle aspiration. Gastrointest. Endosc. 1994; 40:694-9.
9. Keehan E, Cavanagh C, Gergely V. Novel alloy for specialty needle applications. Medical Device Technology, 2009, March/April

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