Original Article

Global Spine Journal
2021, Vol. 11(4) 509-514
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DOI: 10.1177/2192568220912993
journals.sagepub.com/home/gsj

Shape Loss of Autoclaved, Machine-Bent Cobalt-Chrome and Titanium Spine Surgery Rods

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Abstract

Study Design: This was a biomechanical study.

Objective: Shape loss of surgical spine rods has been implicated as a factor leading to postsurgical loss of alignment correction. Our objective was to compare the degree of shape loss in surgical spine rods of different compositions under physiological conditions that were bent before or after being autoclaved.

Methods: 10 CoCr and 10 commercially pure titanium (CPTi) surgical spine rods were contoured using a machine press. Five CoCr and 5 CPTi rods were bent before being autoclaved (preoperative bent group); 5 CoCr and 5 CPTi rods were bent after being autoclaved (intraoperative bent group). All rods were immersed in a phosphate-buffered saline bath at body temperature (37.2°C ± 2°C). Changes in radius of curvature were measured at different time intervals over an 8-week course using a high-definition scanner.

Results: Each rod demonstrated shape loss in radius of curvature (range = 1.04-9.99 mm) over the duration of the study. Intraoperatively bent CPTi rods demonstrated the largest shape loss (range = 8.73-9.99 mm; median 9.33 mm; $P < .01$). Preoperatively bent CPTi (range = 1.04-1.71 mm; median = 1.39 mm; $P < .01$) and intraoperatively bent CoCr (range = 1.11-2.11 mm; median = 2.01 mm; $P < .01$) rods underwent the least amount of shape loss.

Conclusion: CPTi spinal rods bent after autoclave may lead to considerable loss of alignment correction. In addition, our results suggest that preautoclave bent CPTi and CoCr spinal rods bent after autoclave may be a more ideal choice of implant because they may provide more resistance to shape loss over time.

Keywords

spine surgery, spine rods, autoclave, shape loss, titanium, cobalt chrome

Introduction

Commercially pure titanium (CPTi) rods are often used in instrumentation of the spine. Its favorable structural properties include resistance to fatigue, decreased density, lower modulus of elasticity, and minimal artifact on magnetic resonance or computed tomography imaging.[1-4] These properties allow for a low-weight, yet more durable construct. In a 2012 UK survey, 88% of spine surgeons questioned preferred the use of titanium implants over stainless steel (SS) and cobalt chrome (CoCr), in the instrumentation of the spine for the purpose of correcting scoliosis.[5] Although titanium has many benefits because of its aforementioned properties, recent studies have shown that it is more prone to shape loss after contouring when compared with SS.[6,7] This should be of importance to spine surgeons because shape loss of surgical spine rods has been implicated as a possible contributing factor leading to postsurgical loss of

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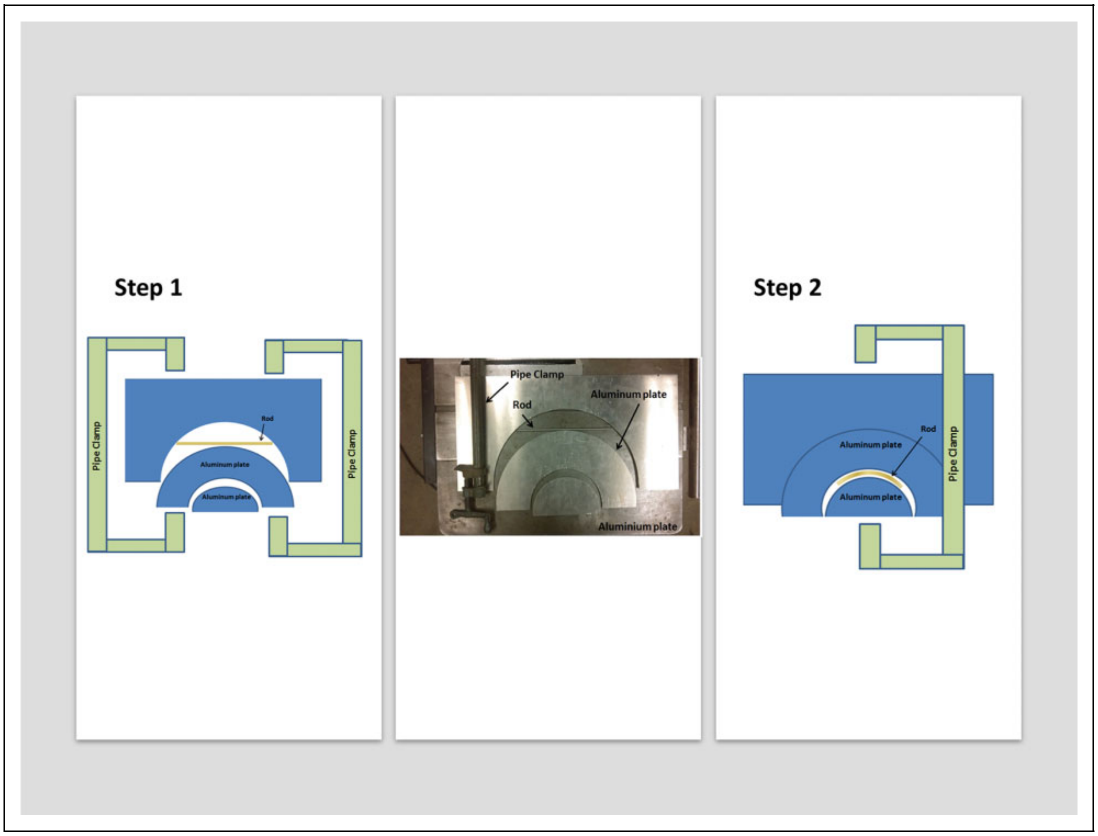

Figure 1. Spine rod machine bending apparatus: rods bent with a single radius of curvature of 100 mm.

sagittal balance and instrumentation failure at the most superior end of the fixation construct.[3,6] Altogether, this has led to further investigation of other metals and alloys that are more resistant to shape loss after bending and, thus, likely more ideal for use as implants in surgery to correct spinal deformity.

One such alloy is CoCr. Recently, the use of CoCr rods is gaining popularity because of its enhanced static strength characteristics. In a recent engineering study, CoCr was found to have a greater fatigue life than CPTi constructs at all load levels tested.[8] This study seeks to determine the degree of shape loss of CoCr rods when compared with CPTi rods in a physiological environment because multiple studies have shown that fatigue of different metals is increased with in vivo conditions.[9-14] Additionally, we examined shape loss when rods were bent both before and after autoclave. The authors hypothesize that the shape loss of CoCr rods will be significantly less than that of CPTi rods.

Materials and Methods

A total of 20 surgical spine rods were obtained as a donation from Stryker Spine (Stryker Co, Kalamazoo, MI), 10 CPTi and 10 CoCr. Each rod was 5.5 mm in diameter and 200.0 mm in length. Each rod was also beveled at one end to improve measurement. The rods were separated into 4 testing groups: 5 CPTi rods were autoclaved then bent (CPTi intraoperative bent group), 5 CPTi rods were bent then autoclaved (CPTi preoperative bent group), 5 CoCr rods were autoclaved then bent (CoCr intraoperative bent group), and 5 CoCr rods were bent then autoclaved (CoCr preoperative bent group).

Rod Preparation

Each rod was bent using a custom-made machine press single curvature (C-shaped) mold to an exact radius of curvature of 100 mm. This custom machine press consisted of a pipe clamp and a series of aluminum plates (Figure 1). Each rod was aligned in between the aluminum plates and, utilizing the pipe clamp, was pressed to the correct specifications. Autoclaving occurred according to surgical implant standards either before or after machine bending. The rods were placed in the autoclave and treated with 4 minutes of steam followed by 20 minutes of drying at 270°F (132.3°C) and 31 PSI. The rods were then removed from the autoclave and allowed to cool for 3 hours. Rods that were bent before autoclaving were scanned before and after autoclaving to assess any shape loss that may have occurred during the autoclave process. Rods that were autoclaved straight and then bent were designated the *intraoperative bent* group. This group represents intraoperative bending of a straight rod to fit a fusion construct. Rods that were bent prior to autoclaving were designated the *preoperative bent* group. This group represents preoperatively bent rods that are contoured and sterilized prior to use in a specific fusion construct.

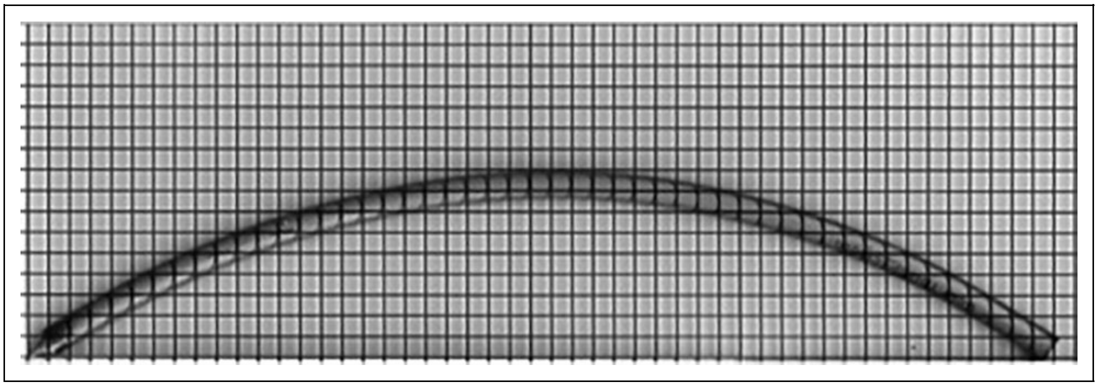

Figure 2. Rods placed on 4-mm scanning graph that was utilized for measurement of shape loss.

Shape Loss Evaluation

After the rods were prepared, they were separated, placed into glass containers, and completely immersed in a phosphate-buffered saline (PBS Catalog No. BP39920, Fisher Scientific) solution and incubated at physiological temperatures 37.2°C (±2°C; Catalog No. 13-255-26, Fisher Scientific). The rods were only removed and dried for imaging, which was done at 2 days and then every 2 weeks' interval for a total duration of 8 weeks. The rods were imaged with a 720 dpi scanner. Prior to scanning the rods, a transparent grid, was fixed to the cover of the scanner (Figure 2). A frame was constructed to outline this grid and affix to the scanning panel, so that the rods would be placed in the same location for each imaging session. Images were saved digitally for measurement within Adobe Photoshop (Adobe Systems Inc, San Jose, CA), which allowed enhanced measurement accuracy of the rods, to within one-hundredth of a millimeter. Blinded reviewers came to a consensus agreement on the placement of measurement parameters for each rod, and a measurement was recorded.

Statistical Analysis

Shape loss measurements were collected and mean changes examined between experimental groups at each time interval. A biostatistician at our institution was employed to oversee statistical analysis of the data. This was accomplished using a Mann-Whitney *U* test to assess significant difference between the radius of curvature of CoCr and CPTi rods.

Table 1. Median Change in Radius of Curvature Over Time: Intraoperatively Bent After Autoclave.

Rod Type	Duration (days)	Median Δ in Radius (mm)
CPTi	2	4.99
	14	7.69
	28	8.85
	42	9.15
	56	9.33
CoCr	2	0.14
	14	1.24
	28	1.95
	42	2.01
	56	2.01

Abbreviation: CPTi, commercially pure titanium.

Table 2. Median Change in Radius of Curvature Over Time: Preoperatively Bent Before Autoclave.

Rod Type	Duration (days)	Median Δ in Radius (mm)
CPTi	2	0.36
	14	0.45
	28	0.88
	42	1.03
	56	1.19
CoCr	2	0.16
	14	1.28
	28	2.38
	42	2.46
	56	2.47

Abbreviation: CPTi, commercially pure titanium.

Results

Each spine rod experienced shape loss at all time intervals (Tables 1 and 2). The greatest change in rod radius of curvature was seen in the intraoperative bent CPTi (range = 8.73-9.99 mm; median = 9.33 mm) group. Conversely, the lowest change to the rod radius of curvature was observed in the preoperative bent CPTi group (range = 1.04-1.71 mm; median = 1.39 mm). The difference between these 2 CPTi cohorts was statistically significant ($P < .01$; Tables 3 and 4). When comparing CoCr rods, we determined a greater change to the radius was appreciated in the intraoperatively bent (range = 1.11-2.11 mm; median = 2.01 mm) compared with the preoperatively bent CoCr rods (range = 1.04-1.71 mm; median = 1.39 mm).

Between the intraoperative bent rods, the CPTi rods demonstrated a significantly greater increase in shape loss when compared with CoCr rods ($P < .01$). However, among the preoperative bent group, CPTi rods demonstrated less shape loss in their radius of curvature compared with CoCr rods ($P < .01$).

Table 3. Total Shape Loss in Radius of Curvature After 8 Weeks, by Rod: Intraoperatively Bent After Autoclave.

Rod Number	CoCr (mm)	CPTi (mm)
1	1.11	8.73
2	1.96	9.02
3	2.01	9.33
4	2.10	9.92
5	2.11	9.99
Median	2.01	9.33

Abbreviation: CPTi, commercially pure titanium.

Table 4. Total Shape Loss in Radius of Curvature After 8 Weeks, by Rod: Preoperatively Bent After Autoclave.

Rod Number	CoCr (mm)	CPTi (mm)
1	2.06	1.04
2	2.31	1.19
3	2.47	1.39
4	2.58	1.51
5	3.56	1.71
Median	2.47	1.39

Abbreviation: CPTi, commercially pure titanium.

Discussion

Shape loss of surgical spine rods has been implicated as a possible contributing factor leading to postsurgical loss of alignment correction. The clinical relevance of shape loss was suggested by Noshchenko et al[7] to be detrimental to the spine fusion constructs, even though it was relatively small.[7] This is of concern because previous literature has also suggested that CPTi rods are prone to shape loss after autoclaving and manual bending.[6] This was reproduced in our study because all CPTi rods (in addition to all CoCr rods) demonstrated statistically significant loss of shape over time. The change in their radius of curvature ranged from 1.04 to 9.99 mm across all groups. This was likely because of inadequate overall plastic deformation being created in our rods, which therefore resulted in excessive recoil after the rods were removed from the machine press. Although the clinical significance of this shape loss over time may be of little importance to spine surgeons if the goal of surgery is for in situ stabilization, if deformity correction and maintenance become a priority, then a surgeon may want to consider overcorrecting a rod construct knowing that they will encounter shape loss over time.

When compared with their shape immediately after bending, CPTi rods underwent significantly greater shape loss in the intraoperatively bent group compared with the prebent group. On the other hand, CoCr rods in the intraoperatively bent groups underwent significantly less shape loss than their CPTi counterparts under the same conditions. The median change in radius of curvature for the intraoperative group of CoCr rods was 2.01 mm compared with 9.33 mm for the corresponding CPTi group. This, therefore, suggests that it would be a more ideal rod choice when intraoperative bending is absolutely required for custom fit instrumentation.

Conversely, CoCr rods in the preoperative bent group underwent significantly more shape loss than CPTi rods. In the preoperative bent group, the average change in radius of curvature for the CPTi rods was 1.39 mm compared with 2.49 mm for the CoCr rods. This finding suggests that a preoperatively bent CPTi rod is less prone to shape loss than a preoperatively bent CoCr rod and, thus, may be the ideal rod choice when intraoperative bending is not required.

Overall, our findings indicate that when shape loss of a construct is of utmost concern, as in correction of spinal deformity, preoperatively bent CPTi rods or intraoperatively bent CoCr rods should be considered. The selection between these 2 groups should depend on patient anatomy and whether or not it dictates the need for intraoperative bending. This recommendation is consistent with a study by Burger et al,[6] which found that CPTi rods contoured during surgery will lose their shape, possibly having an adverse effect of the sagittal balance of the instrumentation during the healing process.

Similar to prior studies, the rate of shape loss was highest during the first 2 days of the study and then decreased to a rate approaching zero by 8 weeks.[6,7] This early shape loss is likely a result of elastic recoil. That is, the amount of deformation created was not enough to surpass the yield point. Of note, our first measurement was done 2 days after bending, but it is quite possible that this elastic recoil was instantaneous or mostly occurred at an earlier time point. As a result, this elastic recoil is likely not a major problem because it can feasibly be compensated for in the operating room by the surgeon rebending the rod until the desired amount of plastic deformation is obtained.

Furthermore, all rods demonstrated shape loss at all time intervals. This delayed recoil may be because rods that have been plastically deformed slowly recoil over time to assume a new point zero in their shape, which takes a longer period of time as that seen in immediate elastic recoil. This so-called elastic recovery during plastic deformation can potentially be a major problem in that it is more difficult for the surgeon to control because it takes place over a longer period of time. Having full knowledge of this phenomenon, however, a surgeon may or may not overbend their rods and/or implement a short postoperative course of external orthosis wear to supplement resistance to this delayed shape loss until radiographic signs of fusion.

All rods demonstrated both immediate and delayed recoil. When this type of shape loss is observed, it indicates the presence of both elastic and plastic deformation.[15] After the deforming force is removed, a portion of the rod that was elastically deformed will begin to recoil to its original shape, whereas the portion of the rod plastically deformed will have a delayed and limited recoil to its new baseline shape. Intraoperatively, it is quite possible that the portions undergoing immediate recoil after the temporary elastic deforming force has been removed can be rebent by the surgeon with enough plastic deformation to get a more permanent shape change. However, the inevitable delayed recoil that these portions and the others that had originally undergone enough plastic deformation will experience will be difficult to control for as previously stated. A potential solution, nevertheless, would be to overbend the rods knowing that some delayed shape loss will occur. The degree to which one should overbend to compensate for this expected delayed shape loss, however, is unknown because this is a phenomenon that has not been heavily researched.

Whereas this study dealt with the shape loss of unfixed spine surgery rods, other studies have supported the idea that CoCr is superior to other metals when contouring for fixed constructs as well. A study by Lindsey et al[16] sought to characterize the effects of fatigue performance of CoCr, CPTi, and SS rods. This study found that the endurance limit of CoCr rods was at least 25% higher than that of CPTi and SS rods and superior at all conditions tested for intraoperative bending. Another study by Serhan et al[17] demonstrated that CoCr rods provided the greatest correctional force when approximating the spine surgery rod to a spine in a mock intraoperative setting. Data from this study further mirrored our own in regard to the rigidity of preoperative bent CPTi rods. In our study, this group exhibited the least amount of shape loss, maintaining its shape better than CoCr rods in the preoperative bent group. These findings are consistent with a prior study that concluded that fixed, preoperative bent CPTi rods maintained 90% of their shape, a significantly improved rate compared with CoCr, SS, and even ultrahigh strength SS.[16] This is clinically relevant as precontoured rods continue to gain popularity, with some surgeons preferring these to reduce a deformed spine to a rod construct.

Although the results from this study are in agreement with similar studies examining rod shape loss, there are some limitations to our study. Only 5 rods were evaluated in each group, leading to our study being underpowered. Furthermore, it was not possible to blind our evaluators as to which rod they were evaluating, introducing the potential for observer bias. Our study utilized scanned digital photographs and a measuring tool accurate to 0.01 mm; for this reason assessing interobserver and intraobserver variability was not deemed necessary. Finally, the rods in our study were evaluated unfixed and unloaded; therefore, it is unclear if the degree of shape loss observed would change if the rods were fixed and/or loaded as they would be in a real live scenario. Nevertheless, this study, along with several others mentioned, develops a good fund of knowledge on the potentials for shape loss in preoperatively bent and intraoperatively bent spinal rods. However, further investigation is warranted to evaluate a larger sample size, along with in vivo studies to solidify clinical correlation.

Conclusion

This study demonstrated that the intraoperatively bent CPTi spine rod offers little resistance to shape loss compared with preoperatively bent CPTi spine rods and intraoperatively bent CoCr spine rods. We, therefore, recommend that careful consideration should be given to the use of CPTi spine rods that must be bent intraoperatively because this may lead to considerable loss of alignment correction. In addition, preoperatively bent CPTi and intraoperatively bent CoCr spinal rods may be more ideal choices of implant to be used in alignment correction because they may provide more resistance to shape loss over time.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Surgical implants were provided by Stryker; NC royalties were received from Globus.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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