

## Arthroplasty in the military: a preliminary experience with ProDisc-C and ProDisc-L

LUIS M. TUMIALÁN, M.D., LCDR, MC, USN, RYAN P. PONTON, M.D., LT, MC, USN, ANGELINA GARVIN, B.A., CCRP, AND WAYNE M. GLUF, M.D., CDR, MC, USN

*Department of Neurosurgery, Naval Medical Center San Diego, California*

**Object.** The introduction of cervical and lumbar arthroplasty has allowed for management of cervical radiculopathy and lumbar degenerative disease in patients with the preservation of motion at the affected segment. While the early clinical outcomes of this technology appear promising, it remains unclear what activity limitations should be imposed after surgery in patients with these implants. This is of particular interest in military personnel, who may be required to return to a rigorous level of activity after surgery. The goals of the FDA trials evaluating various disc arthroplasty devices were to establish safety, efficacy, and equivalency to arthrodesis. Information regarding the level of physical performance attained and restrictions or limitations is lacking, as these were outside the objectives of these trials. Nevertheless, these data are essential for the military surgeon, who is tasked with guiding the postoperative management of patients treated with arthroplasty and returning them to full duty. While there is a single report of clinical results of lumbar arthroplasty in athletes, at this writing, there are no reports of either cervical or lumbar arthroplasty in active duty military personnel.

**Methods.** The surgical database at a single, tertiary care military treatment facility was queried for all active-duty patients who underwent placement of either a cervical or lumbar arthroplasty device over a 3-year period. The authors performed a retrospective chart review to collect patient and procedural data including blood loss, length of hospital stay, tobacco use, age, rank, complications, and ability to return to full unrestricted active duty. Arthroplasty cohorts were then compared to historical controls of arthrodesis to ascertain differences in the time required to return to full duty.

**Results.** Twelve patients were identified who underwent cervical arthroplasty. All patients returned to unrestricted full duty. This cohort was then compared with 12 patients who had undergone a single-level anterior cervical discectomy and fusion. The average time to return to unrestricted full duty for the arthroplasty group was 10.3 weeks (range 7–13 weeks), whereas that in the fusion group was 16.5 weeks. This difference between these 2 groups was statistically significant ( $p = 0.008$ ). Twelve patients were identified who underwent lumbar arthroplasty. Ten (83%) of 12 patients in this group returned to unrestricted full duty. In patients who returned to full duty, it took an average of 22.6 weeks (range 12–29 weeks). This cohort was then compared with one in which patients had undergone anterior lumbar interbody fusion. Eight (67%) of 12 patients in the lumbar arthrodesis group returned to unrestricted full duty. In patients who returned to full duty, it took an average of 32.4 weeks (range 25–41 weeks). This difference was not statistically significant ( $p = 0.156$ ).

**Conclusions.** The preliminary experience with cervical and lumbar arthroplasty at the authors' institution indicates that arthroplasty is comparable with arthrodesis and may actually expedite return to active duty. Patients are capable of returning to a high level of rigorous training and physical performance. There are no apparent restrictions or limitations that are required after 3 months in the cervical patient and after 6 months in the lumbar patient. Further prospective studies with long-term follow-up are indicated and will be of value when determining the role of arthroplasty compared to arthrodesis in the active-duty population. (DOI: 10.3171/2010.1.FOCUS102)

**KEY WORDS** • active-duty military • arthroplasty • cervical • lumbar • outcomes

**S**INCE the FDA's approval of lumbar arthroplasty devices in 2004 and cervical devices in 2007, surgeons have rapidly incorporated this technology into clinical practice.<sup>11,20</sup> Over these few years, both cervical and lumbar arthroplasty have been demonstrated to be safe and at least equivalent to arthrodesis in the civilian popu-

lation.<sup>2–5,8,15–17,22</sup> Military patients, however, represent a very different population, especially in certain military communities. The Marines and special operations communities, in particular, have rigorous physical demands that may place extraordinary physiological stresses on the cervical and lumbar spine. Parachute jumps, diving, high-impact water entries, and prolonged runs bearing heavy loads collectively represent only some of the physical demands required of these service members. While intradiscal pressures while performing tasks of daily life have been measured, the repetitive axial and rotational

*Abbreviations used in this paper:* ACDF = anterior cervical discectomy and fusion; ALIF = anterior lumbar interbody fusion; EBL = estimated blood loss; PLL = posterior longitudinal ligament; PRT = physical readiness test.

**TABLE 1: Inclusion and exclusion criteria**

Inclusion Criteria	Exclusion Criteria
1) age between 18 & 50 yrs	1) >1 cervical or lumbar vertebral level requiring treatment
2) on full, unrestricted active duty preop	2) undergone or in the process of a Physical Evaluation Board
3) neck, arm pain, or neurological deficit confirmed by x-ray and CT or MRI to include any 1 of the following:	3) neck or arm pain of unknown etiology
i. herniated nucleus pulposus	4) active infection—local or systemic
ii. spondylosis	
iii. loss of disc height	5) spine malignancy or tumor

stress and sudden increase in external forces associated with high impact activities in the military have not been studied.<sup>10,19,21</sup> The magnitude of these forces remains largely unknown. This creates a difficulty in predicting the behavior of a modular implant, such as the ProDisc, under such conditions.

Because the goals of the FDA trials with various arthroplasty devices were to establish safety, efficacy, and equivalence to arthrodesis, we lack information regarding the level of physical performance attained and restrictions or limitations in arthroplasty data.<sup>4,7,8,12,17,18,22</sup> However, because the physical performance expectation is much higher in military patients, this data are essential for the military surgeon when guiding the postoperative management of a soldier, Marine, sailor, or airman to return to unrestricted full duty.

The authors have previously established the capacity of treated patients' return to unrestricted full duty after either lumbar or cervical fusion, indicating that single-level arthrodesis does not preclude the return to previous high-level physical performance (Pontan R, Tumialán L, Garvin A, Gluf W: "Rate of return to military active duty after single level and two level anterior cervical discectomy and fusion: a 4 year retrospective review" and Tumialán L, Ponton R, Riccio A, Gluf W: "Rate of return to military active duty after single level lumbar interbody fusion: a 5 year retrospective review." Oral Platform Presentations at the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves. Orlando, Florida, 2010). With the introduction of arthroplasty, the logical questions become: What do these stresses do to an arthroplasty device and are they compatible with unrestricted full duty? Furthermore, we were not clear how quickly individuals may return to high levels of activity or what limitations, if any, should be imposed on these individuals.

With this in mind, we reviewed our preliminary experience with cervical and lumbar arthroplasty in the military over the past 3 years at a single military treatment facility. Two cohorts, one lumbar and one cervical, are retrospectively reviewed in this report. Particular attention is drawn to the time required to return to active duty and the level of function attained after surgery.

The preliminary experience with cervical and lumbar arthroplasty in our military patients indicates that it is comparable with arthrodesis and may actually expedite a return to active duty. Further prospective studies with long-term follow-up are indicated and will be of value

when determining the role of arthroplasty compared with arthrodesis in military personnel.

## Methods

The surgical database at a single, tertiary care military treatment facility was queried for all active-duty patients who underwent placement of either a cervical or lumbar arthroplasty device between April 2007 and October 2009. We applied the same inclusion and exclusion criteria that were used in the FDA trials (Table 1).<sup>16,22</sup> In addition, the governing instructions from the Bureau of Medicine and Surgery, as well as the Naval Aerospace Medical Institute, do not permit members of the aviation community to undergo arthroplasty, and so all aviators were excluded from arthroplasty.

Either the ProDisc-C or ProDisc-L (Synthes Spine) was used in all patients. A retrospective chart review was performed to collect patient and procedural data to include EBL, hospital length of stay, tobacco use, age, rank, complications, and ability to return to full unrestricted active duty. Patients underwent follow-up evaluations at 1, 3, 6, 12, and 24 months (when applicable). Flexion and extension radiographs were obtained at each evaluation to demonstrate preservation of motion and to rule out device-related complications. We questioned each service member about the level of performance attained, in particular the capacity to perform a PRT, combat fitness test (applicable only to Marines), and return to their previous level of performance (that is, parachute jumping, diving, running). Data obtained in each cohort was then compared with an age- and level-matched individuals who had undergone ACDF or ALIF. The primary focus of this comparison was to determine differences in time to return to full duty.

### *Surgical Technique*

*Cervical Spine.* A Smith-Robinson technique was used to approach the affected cervical disc level. After a complete discectomy was performed, including removal of the cartilaginous endplates, patients underwent arthrodesis in which cortical or cortical cancellous allograft was used with a dynamic plate or arthroplasty. In patients who underwent arthroplasty, the technique described in previous reports was used.<sup>3,16</sup> The midline was marked on the vertebral bodies. The PLL was resected in all cases. With

## A preliminary experience with the ProDisc in the military

the disc space distracted, an appropriate size disc was trialed. A milling drill guide was introduced overtop of the trial and used to create keel cuts in the vertebral body. The keel cuts were then cleared of all bony debris and the cervical arthroplasty device (ProDisc-C) was inserted under direct fluoroscopic imaging.

**Lumbar Spine.** All patients with lumbar lesions underwent surgery via an open anterior retroperitoneal. A vascular surgeon assisted in the approach. After fluoroscopic confirmation of the level, a complete discectomy was performed, including removal of the cartilaginous endplates. In patients undergoing lumbar fusion, either lumbar tapered cages with recombinant human bone morphogenetic protein-2 or femoral ring allograft was used with a plate. In patients undergoing arthroplasty, intervertebral body distractors were used to distract the disc space and facilitate exposure of the PLL. The PLL was divided when necessary, ensuring parallel distraction of the disc space. An appropriate disc trial was then sized and placed into the disc space. An anteroposterior fluoroscopic image was obtained to ensure midline. Keel cuts were then made into the rostral and caudal vertebral bodies, and the arthroplasty device secured under fluoroscopic guidance as described in previous reports.<sup>22</sup>

### Statistical Analysis

Analysis was based on pairings of patients for demographic variables. Descriptive statistics included mean and standard deviations for age, EBL, operative time, and time required to return to active duty. Difference between ProDisc-C and ACDF pair members, as well as ProDisc-L and ALIF pair members, were tested against zero difference by Wilcoxon signed-rank test.

## Results

### Cervical Spine

Twelve patients were identified who underwent cervical arthroplasty during the study period. They were all men. The average age at the time of surgery was 36.5 years. The treated levels were C5–6 (8 patients) and C6–7 (4 patients). The average operating time was 165.3 minutes and EBL was 59.5 ml. All patients returned to unrestricted full duty. No restrictions or limitations were self-identified by this group with regard to performance status after 3 months. This cohort was then age matched and level matched with 12 patients who had undergone a single-level ACDF and had returned to full duty. The average age at the time of surgery for the fusion group was 36.1 years. The mean operating time was 129 minutes and EBL was 25.5 ml. The average time to return to unrestricted full duty for the arthroplasty group was 10.3 weeks (range 7–13 weeks), whereas that for the fusion group was 16.5 weeks. This difference between these 2 groups was statistically significant ( $p = 0.008$ ) (Table 2). Five of the 7 Navy SEALs in this group reported returning to free-fall parachute jumping and high-impact water entries. Subsequent radiographic imaging of these patients did not demonstrate implant migration or sub-

**TABLE 2: Comparison of cervical and lumbar ProDisc arthroplasty with fusion**

Op Group & Variables	Arthroplasty	Arthrodesis	p Value
<b>ProDisc-C vs ACDF</b>			
no. of patients	12	12	
average age	36.5	36.1	
no. returned to full duty	12	12	
time to full duty (wks)	10.3	16.5	0.008
<b>ProDisc-L vs ALIF</b>			
no. of patients	12	12	
average age	37.3	40	
no. returned to full duty	10	8	
time to full duty (wks)	22.6	32.4	0.156

sidence after these activities. The mean follow-up period for the arthroplasty group was 12.2 months (range 3–26 months).

### Lumbar Spine

Twelve patients were identified who underwent lumbar arthroplasty during the study period. There were 10 men and 2 women. The average age at the time of surgery was 37.3 years. The treated levels were L5–S1 (7 patients) and L4–5 (5 patients). The average operating time and EBL were 235.8 minutes and 209.5 ml, respectively. Ten (83%) of 12 patients in the lumbar arthroplasty group returned to unrestricted full duty. One patient was separated from the military for persistent symptoms, and one patient remains on limited-duty status at this writing. One patient experienced right S-1 radiculopathy after arthroplasty and required a foraminotomy and decompression of the nerve root after arthroplasty (see below). He eventually returned to full duty. In patients who returned to full duty, it took an average of 22.6 weeks (range 12–29 weeks). This cohort was then age matched and level matched to 12 patients who had undergone a single-level ALIF. The average age for this group was 40 years. The average operative time and blood loss were 143.1 minutes and 102.5 ml, respectively. Eight (67%) of 12 patients in the lumbar arthrodesis group returned to unrestricted full duty. In patients who returned to full duty, it took an average of 32.4 weeks (range 25–41 weeks). Although there was an apparent difference between the mean time to return to active duty, this difference was not statistically significant ( $p = 0.156$ ), likely because of the limited number of pairs available for statistical analysis (Table 2). The mean follow-up period was 10.7 months (6–26 months).

### Complications

In 1 patient in the cervical arthroplasty group we observed a progressive osteolysis from the rostral keel at 9 months. The patient required removal of the device and conversion to an anterior cervical fusion. This unusual complication was attributed to a device-related immune-mediated reaction to one of the alloys in the implant. One patient in the lumbar arthroplasty group experienced new-onset S-1 radiculopathy after surgery. Subsequent

imaging demonstrated that the device was 4 mm off the midline. The patient underwent a posterior decompression of the S-1 nerve root and would return to unrestricted full duty. There was one vascular injury in the lumbar arthroplasty group, which occurred during exposure of the L4–5 level. The injury resulted in an EBL of 600 ml. The injured vessel was repaired primarily at the time of surgery and there were no long-term sequelae. This patient would return to full duty.

### Discussion

The goals of the prospective randomized controlled clinical trials approved by the FDA on the ProDisc-C, ProDisc-L, Bryan, Prestige, and CHARITÉ devices were 2-fold: demonstrate the safety and efficacy of the arthroplasty device and establish that clinical outcomes were not inferior to arthrodesis.<sup>4,7,8,12,16,18,22</sup> In large part, the outcomes of these studies were based on health-related quality of life measures, which included an Oswestry or Neck Disability Index, patient satisfaction, absence of device failure, visual analog scale, and absence of strong narcotic or muscle relaxant. Similar to our study, these trials were performed on a relatively young patient population (average age of 42.8 and 39.2 years in the cervical and lumbar studies, respectively). Nevertheless, there is minimal information regarding restrictions or limitations imposed in the immediate postoperative period or the level of physical activity attained in the arthroplasty group. The authors of these trials did examine work, physical labor, and recreation status at 24 months, but the information is limited and for the most part not applicable to active-duty military.<sup>12,22</sup>

The absence of this clinical information prompted us to review our experience with cervical and lumbar arthroplasty, with a particular emphasis on return to unrestricted full duty and the level of physical performance attained. Thus, while the current literature suggests that the long-term efficacy of arthroplasty in a young active population appears to be equivalent to arthrodesis, the level of activity that can be achieved by an individual who has undergone arthroplasty has not previously been well established. Equally unclear are the restrictions and limitations for an individual in whom an arthroplasty device has been implanted. There is a concern regarding the forces generated during high-impact activities and the effect these activities may have immediately or over time on a modular implant, in particular the ultrahigh-molecular weight polyethylene inlay. Because biomechanical studies have focused on wear and failure over the course of millions of simulation cycles, the consequences of these high external forces on this modular implant are not presently known. The primary goal of this article was to explore these 2 aspects of arthroplasty in a military population to answer the question: can an individual return to his/her previously high level of performance after arthroplasty and, if so, how quickly?

#### *Return to Full Duty and Level of Activity*

Patients in both the cervical and lumbar arthroplasty cohorts returned to full duty on average 6.2 and 9.8 weeks,

respectively, sooner than their arthrodesis counterparts. This difference was statistically significant in the cervical cohort but not the lumbar group. At first glance, this may suggest that the patient treated with arthroplasty has had a better outcome. In actuality, this represents more the limitations imposed by the clinician for a patient within the arthrodesis group than a superior clinical outcome for an arthroplasty patient. With the exception of the aviation community, in which individuals are restricted from undergoing disc arthroplasty by regulation and are required to undergo a minimum of 6 months of limited duty after a cervical or lumbar fusion, the return to unrestricted full duty, to a certain extent, is arbitrary and dependent on the surgeon. For instance, a surgeon may return to duty a service member who works in a more sedentary environment sooner than he would a Marine infantryman who has to bear a 60-lb pack on his return to full duty. Overall, the reluctance of a military surgeon to return an individual to unrestricted full duty after cervical or lumbar fusion is primarily born out of concern for the arthrodesis and the impact it may have on the patient's health. Returning an individual prematurely to unrestricted full duty communicates to that individual and to his/her command that there are no restrictions or limitations. To avoid long-term complications in patients with arthrodesis, we typically defer returning patients to full duty until evidence of a maturing fusion is seen on radiographs or CT scans along with the absence of motion on dynamic plain radiographs.

In patients who underwent arthroplasty, there were no radiographic criteria that would indicate when it would be safe to return to full duty. Thus, when individuals were evaluated and found to have resolution of preoperative symptoms, it was difficult to impose any restrictions or limitations upon them. We found that the patients in our series, especially in the cervical arthroplasty cohort, were returning to their previous levels of activity by their 3-month follow-up, and we therefore released them to unrestricted full duty at that time. One patient in the lumbar arthroplasty cohort successfully completed a PRT, consisting of a 1.5-mile run and maximum sit-ups and push-ups in a 2-minute period only 14 weeks after surgery. Herein lies the difference between the 2 groups: the surgeons are more apt to release an asymptomatic patient treated with arthroplasty sooner to full duty than an asymptomatic patient treated with arthrodesis.

#### *Cervical Spine: Performance Status*

Despite the earlier return to full duty in the cervical arthroplasty group, we identified no significant difference between the arthrodesis and arthroplasty at longer-term follow-up. All patients in the cervical arthrodesis and arthroplasty groups were able to return to full duty by 6 months. Review of the level of performance in the cervical arthrodesis group and cervical arthroplasty group at 6 months demonstrates equivalence in physical performance and the capacity for overseas deployment and shipboard duty. This indicated that these individuals were able to perform a PRT and a combat fitness test (applicable only to the Marines) as well as return to their level of previous training. Special operations members returned

## A preliminary experience with the ProDisc in the military

**TABLE 3: Algorithms for returning treated individuals to active duty**

Treatment Group & Postop Time (Wks)	Activity
<b>ProDisc-C</b>	
0–3	begin nonimpact cardio exercise up to 60 mins daily: Lifecycle, StairMaster, elliptical, & walking are recommended
3–6	begin nonimpact cardio without limitations; begin light weight training at 25–50% of preop capability
7–12	begin impact cardio, including running on treadmill; progress to unlimited cardio by Week 12; advance to full weight training Wks 7–12 in a progressive fashion; cleared to return to dive/parachute duty/deployments
<b>ProDisc-L</b>	
0–3	Begin walking as tolerated
3–6	begin nonimpact cardio & may progress to 60 mins/day
6–10	begin unlimited cardio; light weight training may begin at maximum of 25–50% preop capability; no bent-over rows, squats, or military press
11–12	increase weights & cardio up to 75% of maximum
13–16	continue to increase weight lifting up to full tolerance & cardio (nonimpact)
17–20	begin impact cardio including running on treadmill; progress to unlimited cardio by Wk 20; may resume dive operations at 20 wks; jump operations may begin Wk 26

to parachute jumping, high-impact water entries from helicopters, diving, and long-distance runs while bearing a load. None of the patients in the cervical arthroplasty group required separation from the military for persistent symptoms. As previously stated, in 1 individual in the arthroplasty cohort a conversion to a fusion was required, after which the patient returned to full duty as a Navy SEAL. We found no need to impose restrictions or limitations on the arthroplasty group after 3 months from the date of surgery.

### *Lumbar Spine: Performance Status*

It is no surprise that both the lumbar arthrodesis and arthroplasty groups required substantially more time to return to full duty than the cervical group. Patients in the arthroplasty group returned to full duty after an average of 22.6 weeks, whereas individuals in the arthrodesis group returned to full duty after 32.4 weeks. These 2 groups did not begin to demonstrate equivalence in performance status until 9 months after surgery. Such a trend was previously identified with the Oswestry Disability Index and visual analog scale in the CHARITÉ investigational device exemptions study.<sup>4</sup> On average, it took 9.8 weeks longer for the arthrodesis group to return to full duty, but this was due primarily to the previously listed reasons. Two patients who had undergone lumbar arthroplasty were unable to return to full duty as they were incapable of returning to their previous level of activity. By 6 months, 8 of the remaining 10 in the arthroplasty group had returned to full duty and, by 9 months, all 10 had returned to full duty. In particular, the special operation member and Marines returned to their previous performance status. As mentioned in the *Complications* section, 1 individual required a posterior decompression for new-onset radiculopathy. Despite this, he was able to return to full duty 22 weeks after his initial surgery. This is comparable with the experience reported by Siepe et al.<sup>19</sup> who reviewed data obtained after lumbar arthro-

plasty in athletes. In their series of 39 athletes, they identified that peak performance was reached at 5.2 months after surgery, with 37 (94.9%) of the 39 resuming their previous sporting activity.

### *Patient Selection*

Seven patients in the cervical arthroplasty group were Navy SEALs, another 2 were highly trained operators (1 Marine and 1 landing craft air cushion engineer), and the remaining 3 were high-ranking officers. The lumbar cohort was equally selective, with 1 Navy SEAL, 1 Explosive Ordnance Disposal Technician, and 1 Marine infantryman. Hence, the marked success achieved in this series is unquestionably a result of careful patient selection by the authors. All of the patients treated with cervical arthroplasty returned to their previous high levels of performance and were subsequently deployed, and 83% of the lumbar arthroplasty cohort were capable of the same. Admittedly, the authors are highly selective in choosing which patients undergo arthroplasty. All of the patients selected for arthroplasty were of senior rank, specialized in training, and were highly motivated to return to active duty. In fact, several of the patients in the cervical cohort were selected for arthroplasty to expedite their return to full duty. This undoubtedly impacts the rate of return, time to return, and overall success of the arthroplasty cohorts. Therefore, it would be difficult to extrapolate this preliminary experience to a broader population, even within the military.

### *Return-to-Full-Duty Algorithm*

Given the observations we have made during our preliminary experience with arthroplasty, the authors have generated a return-to-full-duty algorithm for our active-duty arthroplasty patients, which we describe below.

*Cervical Spine.* With the exception of the patient with the device-related complication, all patients in the cervical arthroplasty group returned to unrestricted full duty

by 3 months. Based on this, we now allow individuals to begin nonimpact training as soon as they feel comfortable enough to do so after surgery. Typically, patients begin this during the 1st month after surgery once they are off all narcotic medication. During this time, patients are restricted from parachute jumps, high-impact water entries, impact training, diving, and weight training. Throughout the 2nd month, patients are allowed to engage in light impact and weight training. Provided patients remain asymptomatic, they are allowed to return to high-impact training by the 3rd month. Preservation of motion established on flexion/extension radiographs, complete resolution of preoperative symptoms, and absence of hardware complications permit the return to unrestricted full duty and the release from the limitations listed above by the 3rd month (Table 3).

**Lumbar Spine.** The patients who underwent lumbar arthroplasty took on average twice as long to return to full duty (22.6 weeks) as those in the cervical group, and so the postoperative algorithm above is drawn out over this time. Again patients are restricted from parachute jumps, high-impact water entries, impact training, diving, and weight training in the immediate postoperative period. They are encouraged to begin nonimpact training once off all narcotics, which is seldom before the 2nd month and typically not until the 3rd month. Light impact and weight training are begun during the 4th and 5th month and a fitness for full-duty evaluation is done by the 6th month. Confirmation of the preservation of motion, absence of hardware complications, and resolution of preoperative symptoms allow for the service member to return to unrestricted full duty by the 6th month (Table 3).

#### Future Studies

In addition to prospective longitudinal studies with long-term follow-up, further studies would be warranted to examine the effects of military personnel's high-impact activities on the ultrahigh-molecular weight polyethylene inlay and its interface with the chromium cobalt molybdenum alloy. At this time, implanted devices are simply evaluated by plain radiography, given the scatter caused by both CT and MR imaging. Even macroscopic defects on the polymer that may have been caused by high-energy impacts could not be captured by this current imaging. Because the consequences of the extreme forces on the polymer and the polymer-alloy interface remain outside our current radiographic capacity, techniques such as computer-assisted edge-detection techniques, as reported by McCalden and colleagues<sup>13</sup> (for total hip arthroplasty), may have a role to determine the wear on the polymer and examine the polymer-alloy interface.

#### Conclusions

The preliminary experience with cervical and lumbar arthroplasty at our institution indicates that it is comparable with arthrodesis and may actually expedite a return to active duty. As has been identified in the previous FDA trials, this study confirms that cervical and lumbar arthroplasty are associated with clinical improvements

earlier in the postoperative time period than arthrodesis. Patients are capable of returning to a high level of rigorous training and physical performance, as demonstrated by the special operation patients in this series. There are no apparent restrictions or limitations that are required after 3 months in the cervical spine-treated patient and after 6 months in the lumbar spine-treated patient. Further prospective studies with long-term follow-up are indicated and will be of value when determining the role of arthroplasty compared with arthrodesis in the active-duty population, especially for the conceptual benefit of addressing adjacent-segment degeneration. To that end, we are currently enrolling active-duty military patients into a multicenter prospective outcome trial to evaluate lumbar arthroplasty. The possibility of minimizing adjacent-segment degeneration is of particular interest to the military considering the significant strains already placed on the intact spine; there may be a benefit of arthroplasty relative to arthrodesis. Although preliminary studies support this supposition, this has yet to be conclusively established.<sup>1,6,9,14</sup>

#### Disclosure

No financial support was received for the generation of this study. No grant assistance was received for the generation of this study. The authors have no financial interest in the materials mentioned in this paper. The views expressed in this article are those of the authors and do not reflect the official policy or position of the Department of the Navy, Department of Defense, or the United States Government.

Author contributions to the study and manuscript preparation include the following. Conception and design: LM Tumialán. Acquisition of data: LM Tumialán, RP Ponton, A Garvin. Analysis and interpretation of data: LM Tumialán, RP Ponton. Drafting the article: LM Tumialán. Critically revising the article: LM Tumialán, WM Gluf. Reviewed final version of the manuscript and approved it for submission: LM Tumialán, A Garvin, WM Gluf. Statistical analysis: LM Tumialán, RP Ponton. Administrative/technical/material support: A Garvin. Study supervision: LM Tumialán, WM Gluf.

#### Acknowledgments

The authors are grateful for the assistance rendered by Patrick M. Kearney in data collection, the editorial assistance rendered by Ms. Andrea J. Porter, and the help given by Dr. Robert H. Riffenburgh in statistical analysis.

#### References

1. Ahn PG, Kim KN, Moon SW, Kim KS: Changes in cervical range of motion and sagittal alignment in early and late phases after total disc replacement: radiographic follow-up exceeding 2 years. *J Neurosurg Spine* 11:688–695, 2009
2. Bertagnoli R, Yue JJ, Kershaw T, Shah RV, Pfeiffer F, Fenk-Mayer A, et al: Lumbar total disc arthroplasty utilizing the ProDisc prosthesis in smokers versus nonsmokers: a prospective study with 2-year minimum follow-up. *Spine* 31:992–997, 2006
3. Bertagnoli R, Yue JJ, Pfeiffer F, Fenk-Mayer A, Lawrence JP, Kershaw T, et al: Early results after ProDisc-C cervical disc replacement. *J Neurosurg Spine* 2:403–410, 2005
4. Blumenthal S, McAfee PC, Guyer RD, Hochschuler SH, Geisler FH, Holt RT, et al: A prospective, randomized, multicenter Food and Drug Administration investigational device exemptions study of lumbar total disc replacement with the

## A preliminary experience with the ProDisc in the military

- CHARITÉ artificial disc versus lumbar fusion: part I: evaluation of clinical outcomes. **Spine** **30**:1565-1575, 2005
5. Chung SS, Lee CS, Kang CS: Lumbar total disc replacement using ProDisc II: a prospective study with a 2-year minimum follow-up. **J Spinal Disord Tech** **19**:411-415, 2006
  6. Cunningham BW, McAfee PC, Geisler FH, Holsapple G, Adams K, Blumenthal SL, et al: Distribution of in vivo and in vitro range of motion following 1-level arthroplasty with the CHARITÉ artificial disc compared with fusion. **J Neurosurg Spine** **8**:7-12, 2008
  7. Guyer RD, McAfee PC, Banco RJ, Bitan FD, Cappuccino A, Geisler FH, et al: Prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of lumbar total disc replacement with the CHARITÉ artificial disc versus lumbar fusion: five-year follow-up. **Spine J** **9**:374-386, 2009
  8. Guyer RD, McAfee PC, Hochschuler SH, Blumenthal SL, Fedder IL, Ohnmeiss DD, et al: Prospective randomized study of the CHARITÉ artificial disc: data from two investigational centers. **Spine J** **4** (6 Suppl):252S-259S, 2004
  9. Hilibrand AS, Robbins M: Adjacent segment degeneration and adjacent segment disease: the consequences of spinal fusion? **Spine J** **4** (6 Suppl):190S-194S, 2004
  10. Ledet EH, Sachs BL, Brunski JB, Gatto CE, Donzelli PS: Real-time in vivo loading in the lumbar spine: part I. Interbody implant: load cell design and preliminary results. **Spine** **25**:2595-2600, 2000
  11. McAfee PC: The indications for lumbar and cervical disc replacement. **Spine J** **4** (6 Suppl):177S-181S, 2004
  12. McAfee PC, Cunningham B, Holsapple G, Adams K, Blumenthal S, Guyer RD, et al: A prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of lumbar total disc replacement with the CHARITÉ artificial disc versus lumbar fusion: part II: evaluation of radiographic outcomes and correlation of surgical technique accuracy with clinical outcomes. **Spine** **30**:1576-1583, 2005
  13. McCalden RW, Naudie DD, Yuan X, Bourne RB: Radiographic methods for the assessment of polyethylene wear after total hip arthroplasty. **J Bone Joint Surg Am** **87**:2323-2334, 2005
  14. McCormick PC: The adjacent segment. **J Neurosurg Spine** **6**:1-4, 2007
  15. Mummaneni PV, Burkus JK, Haid RW, Traynelis VC, Zdeblick TA: Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled clinical trial. **J Neurosurg Spine** **6**:198-209, 2007
  16. Murrey D, Janssen M, Delamarter R, Goldstein J, Zigler J, Tay B, et al: Results of the prospective, randomized, controlled multicenter Food and Drug Administration investigational device exemption study of the ProDisc-C total disc replacement versus anterior discectomy and fusion for the treatment of 1-level symptomatic cervical disc disease. **Spine J** **9**:275-286, 2009
  17. Sasso RC, Smucker JD, Hacker RJ, Heller JG: Artificial disc versus fusion: a prospective, randomized study with 2-year follow-up on 99 patients. **Spine** **32**:2933-2932, 2007
  18. Sasso RC, Smucker JD, Hacker RJ, Heller JG: Clinical outcomes of BRYAN cervical disc arthroplasty: a prospective, randomized, controlled, multicenter trial with 24-month follow-up. **J Spinal Disord Tech** **20**:481-491, 2007
  19. Siepe CJ, Wiechert K, Khattab MF, Korge A, Mayer HM: Total lumbar disc replacement in athletes: clinical results, return to sport and athletic performance. **Eur Spine J** **16**:1001-1013, 2007
  20. Singh K, Vaccaro AR, Albert TJ: Assessing the potential impact of total disc arthroplasty on surgeon practice patterns in North America. **Spine J** **4** (6 Suppl):195S-201S, 2004
  21. Wilke H, Neef P, Hinz B, Seidel H, Claes L: Intradiscal pressure together with anthropometric data—a data set for the validation of models. **Clin Biomech (Bristol, Avon)** **16** (Suppl 1):S111-S126, 2001
  22. Zigler J, Delamarter R, Spivak JM, Linovitz RJ, Danielson GO III, Haider TT, et al: Results of the prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement versus circumferential fusion for the treatment of 1-level degenerative disc disease. **Spine** **32**:1155-1163, 2007

---

Manuscript submitted January 13, 2010.

Accepted January 26, 2010.

Address correspondence to: Lt. Commander Luis M. Tumialán, M.D., MC, USN, Naval Medical Center San Diego, 34800 Bob Wilson Drive, San Diego, California 92134. email: luis.tumialan@med.navy.mil.