# Spinal Artificial Implant Mechanics and Ossification Issues

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**Abstract:** Spinal implants are used to treat patients with spinal disorders. Implants have different designs, albeit with the same ultimate objective. They can belong to the constrained or unconstrained types. While a large number of implants and designs are available, few have been approved by the United States Federal Drug Administration. The development of the implant itself, tests, and modeling from mechanical and biomedical engineering perspectives are done before using them on patients. While these implants are routinely developed for civilian populations, military doctors are increasingly using them because of the potential advantages. However, an unintended consequence of the use of these artificial disc devices is the formation of the bone outside the skeletal system wherein it is not normal. This is called heterotopic ossification. Earlier presented data are reviewed. Specifically, this study evaluated these important medical and bioengineering issues for different implant designs and conventional surgeries without implants using an animal model and quantified the internal mechanics of the cervical spine under different modes of loading.

**Keywords**: Spinal implants, artificial disc, experimental model, load-sharing, ossification, constrained design of the implant device.

## Introduction

Spinal implants are used to treat patients with spinal disorders. For the human neck, single level spinal implants in the form of artificial discs are increasingly used as an alternative to conventional anterior cervical discectomy and fusion. The insertion of bone grafts with anterior cervical discectomy with or without plates has been in place for a long time (1, 2); however, the use of artificial discs replacing the bone graft and plating procedure is gaining more attention around the world, including developing countries, and studies are available for civilian applications (3, 4). In addition to this advantage, artificial discs are being increasingly used in the military because of its potential for early return-to-duty of personnel (5).

## Proposed Work and Related Literatures

One of the advantages of artificial disc surgeries is the potential to reduce the degeneration of the spine at the adjacent level and preserve motion at the operated level (6-9). In the civilian population, an unwanted consequence of the use of artificial discs is the formation of the bone outside the skeletal system wherein the formation is not normal (3). This is termed as the heterotopic ossification. Medically, heterotopic ossification around the implant has been to shown to occur to the civilian populations (10). Such bone growths are likely to be greater and have greater influence on the load-carrying capacity of the spine in military personnel. This is because this group of the population sustains extraordinary physiological loads, stresses, and strains, due to activities such as diving, parachute jumps, high-impact water entries, and prolonged runs with heavy loads. Operational activities also place additional demand on the operated spine with the implant. The increased demand induces additional loads on the head-neck complex. Because of the increased loading, it is important to understand the biomechanics of these constructs at greater loads, and delineate the mechanical differences between different types of implant designs. This literature review study describes the mechanical differences between ossified and normal spines using an animal model.

## Motivation

The motivation of this study is to analyze the effects of bone growth stemming from different types of spinal implants.

## Problem Domain

This belongs to implants, design and mechanics.

## Problem Definition

While unwanted bony growths do occur with spinal implants in humans, the load-sharing differences in the form of stiffness for example, due to the presence of this growth is less understood in different implant designs.

## Statement

Investigate the effect of heterotopic ossification from modern cervical spine implants.

## Innovative Content

Head-to-head study comparing the ossification issues between different implant designs.

## Problem Formulation or Representation or Design

With the acknowledgment that bony growth occurs due to spinal implants in the human, the study design involved the creation of the ossification using a longitudinal in vivo animal model and quantifying the effects with different implant designs using biomechanical methods.

## Solution Methodologies or Problem Solving

The animals were obtained from a local vendor. They were monitored for a short period of time in the veterinary unit of the VA hospital. They were procured according to the approved Institutional Review Board protocols, anesthetized, pre-surgical radiographs of the cervical spine were obtained, and cervical discectomies were performed at the C3-C4 level. Unconstrained artificial disc, constrained artificial disc, or anterior plating for the anterior cervical discectomy and fusion condition was used to replace the excised disc space. They were maintained and monitored in the local veterinary unit for six months. Radiographs were obtained to follow the recovery process, which permitted the assessment of the fusion properties. The animals were euthanized at the end of the in vivo study. Osteo-ligamentous columns were then excised. Computed tomography (CT) images were obtained to assess the growth of the heterotopic ossifications. They were determined based on the amount of bony growth and the covered space at the anterior-most region of the disc at the level of surgery, C3-C4. The excised spinal columns were fixed at the ends using polymethylmethacrylate. Subfailure/nondestructive biomechanical tests were done in flexion, extension and right lateral bending modes. All these were combined with axial compressive force (11). A failure test was done in the compression-flexion mode. Imaging was done using radiographs and CT. Time varying force and displacement data were obtained using sensors attached to the testing device. From the temporal force and displacement signals, force-displacement curves were obtained under each loading mode for each specimen.

## Results and Sensitivity Analysis

Heterotopic ossification occurred forty percent of unconstrained discs, full bridging of the anterior space with bone growth, and one-quarter of for constrained discs. The failure loading tests resulted in posterior ligamentous injuries. They included facet joint involvements. Facet fractures occurred in one case each with unconstrained artificial disc and constrained implant constructs. Cases with heterotopic ossification responded with purely ligamentous injuries indicating the role of ligaments in these biomechanically loaded specimens. The maximum forces for the three groups of surgeries regardless of ossification will be presented at the conference. Also presented will be the force-deflection responses for each disc type and for each loading type.

## Comparison of Results

Both spinal implants producing heterotopic ossifications parallel reported medical investigations. The rate of heterotopic ossifications has been reported for the unconstrained disc. They have varied over a wide range: from 21 to 76% (12-19). The rate is 71-80% for the constrained disc procedure (15, 17, 20, 21). From a group of 87 patients followed over a two-year period, the following details were reported in a study (22). The unconstrained disc group of patients showed 44.4% of HO occurrence, while the constrained artificial disc group of patients showed 48.0%. The differences were not statistically significant between ($p>0.05$) the two groups of patienrs. In a five-year follow up study of 26 patients with unconstrained disc, 42.3% patients developed ossification, according to another clinical study (23). Recognizing this is a longer follow up evaluation of patients, and while cautioning the generalizability of these results to a larger population, the authors stated the following: the development of heterotopic ossification may influence the adjacent segment spine disease, an important clinical outcome for the patient, and one of the main reasons for the choosing the artificial disc over conventional anterior cervical discectomy and fusion. Although not conclusive, computational modeling studies are being pursued to determine the role mechanical factors and the influence of ossification have on load-sharing within the intervertebral components (24). The present synthesis of a biomechanical study adds another facet in the analysis of mechanical effects of the ossification based on the force-deflection characteristics of the spine and for different spinal implant designs.

## Justification of the Results

This unique head-to-head study used different spinal implants to compare their biomechanical and longitudinal responses with the conventional anterior cervical discectomy and fusion plating procedures. In this literature review (analysis) study, comparisons were made with one-level discectomy and plating because both constrained and unconstrained artificial disc implants are used for single level cervical spine discectomies. A similar procedure would be appropriate to pursue to evaluate other single level-approved discs using this proven method of using an animal model which produced heterotopic ossifications like the human and biomechanical loading applications encountered in the civilian and military populations. Since the present analysis-based study is more focused to the military population, the loading paradigm used in the biomechanical experiments included the addition of compressive forces coupled with a moment load: sagittal flexion, extension and lateral flexion. This approach is in contrast to clinical studies wherein pure moment loads under flexion, extension, lateral bending and axial rotation are applied to test the efficacy of surgical procedures and spinal constructs (25-27). Other implant systems for two levels can also be studied by performing two-level anterior cervical discectomy and fusion (28).

## Conclusion

Force-deflection responses of the spine with spinal implant devices with heterotopic ossification were stiffer than the responses of the spines without the unintended bone formation. This was true for all three modes of loading. However, the change was non-uniform across the three modes. These differences can be attributed to the inherent mode-specific bias, as it well known that the stiffness of the cervical spine in the three anatomical planes are significantly different (29). The three-dimensional anatomy is also complex. The use of the artificial spinal implant devices may have also biased the outcome. Because of the sample size limitations and lack of data from intact spines, additional research is planned to determine the specific role of the type of spinal implant devices on the longitudinal and biomechanical responses. Differing types, constrained versus partially constrained versus fully constrained designs contribute to differing load-sharing, ossifications, and internal mechanics in these spinal implant devices.

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