

Heterotopic Ossification

what it is, how often it occurs, how to minimize it



McAfee Class IV
Heterotopic Ossification

Heterotopic ossification (HO) is the formation of new bone at joints and within soft tissues. It is a multi-factorial bodily response, and has been reported to occur following arthroplasty, spinal cord surgery and trauma. Theories as to cause include genetic predisposition and surgical technique.

Review of cervical arthroplasty literature indicate HO can be expected in a certain percentage of patients and severity. A grading system for describing the severity of HO has been suggested by McAfee as Class I - IV. The attached abstracts from the 2007 NASS Meeting indicate that at a 2 year assessment there was a 12.2% occurrence of Class I, 5.1% as Class II, 3.1% as Class III and 2.0% as Class IV in a cohort of ProDisc-C patients.

The most important point to understand is that while HO can occur in some cases there are steps and techniques that can be performed to minimize the occurrence and severity of HO following cervical disc arthroplasty.

Surgical technique has been shown to be specifically correlated to HO. It is very important to irrigate the wound after each step with the trial, chisel

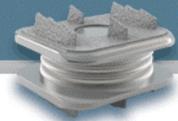
and following insertion of M6-C. Complete coverage of the endplates will help minimize HO risk. Following implantation, the use of bone wax on cut bone surfaces has been suggested. Lastly, the use of a post-operative regimen of Non-Steroidal Anti-Inflammatory drugs (NSAIDs) for 6 weeks has been shown to be effective in minimizing the risk of HO.

Help your surgeons by making them aware of these techniques.

... HO formation following cervical TDR appears to be a result of surgical technique.

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Heterotopic Ossification at the Index Level after ProDisc-C: What is the Clinical Significance?

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BACKGROUND CONTEXT: Post-operative ossification has been reported in the literature for cervical discectomy, some cervical disc replacements, and fusion procedures as well as other cervical surgical treatments.

HO following cervical total disc replacement has been shown to be significantly reduced with the administration of post-operative NSAIDs.

PURPOSE: To determine the prevalence and appearance of HO.

STUDY DESIGN/SETTING: A multi-center, prospective, randomized, clinical trial. NSAIDs were not given post-operatively.

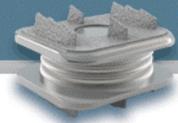
PATIENT SAMPLE: The study was conducted at 14 sites. A total of 209 patients were randomized (106 ACDF, 103 ProDisc-C).

OUTCOME MEASURES: Patients were assessed pre-operatively and post-operatively, 6 weeks, 3, 6, 12, 18 and 24 months. Patients were evaluated by Visual Analog Scale (VAS) Pain and Intensity (Neck and Arm), and VAS Satisfaction, Neck Disability Index (NDI) and SF-36.

METHODS: Radiographs were used to measure heterotopic ossification (HO) at 24 months post-operatively. Heterotopic ossification is indistinguishable from the bone mass associated with fusion in ACDF patients; therefore, heterotopic ossification was not assessed at the treated level in ACDF patients. The classification described by McAfee² is: **Class I:** HO present in islands of bone within soft tissue but not influencing the range of motion of the vertebral motion segment. **Class II:** HO possibly affecting the vertebral range of motion. HO present between the two planes formed by the vertebral endplates but not blocking or articulating between adjacent vertebral endplates or osteophytes. **Class III:** The range of motion of the vertebral endplates is blocked by the formation of HO and/or post-operative osteophytes. **Class IV:** HO causing inadvertent arthrodesis. Bony ankylosis. Bridging trabecular bone continuous between adjacent endplates and less than 3 degrees of motion.

RESULTS: At 24 months post-operatively, radiographic evaluation of Pro-Disc-C patients identified 12.2% as having Class I ossification, 5.1% as Class II ossification, 3.1% as Class III ossification, and 2.0% as Class IV ossification. Class I patients, by definition, do not experience any change in range of motion. The mean flexion/extension range of motion for patients with Grade II or Grade III ossification was 6.4 at 24 months post-operatively, with a range of 2.3 to 16.0. This is comparable to the 8.6 mean flexion/extension range of motion with a range of 0.6 to 24.1 at 24 months post-operatively for the entire ProDisc -C group. In all but one ProDisc -C patient, the radiographic finding of anterior ossification was not associated with any adverse events. When patients with Class II or higher HO were analyzed against the remaining ProDisc-C patient population with regards to NDI, VAS Arm Pain and Intensity, VAS Neck Pain and Intensity, and VAS Satisfaction, there was no statistical difference in outcomes.

CONCLUSIONS: Although HO may exist on radiographs, the clinical significance of such findings is inconsequential. Patients were not experiencing greater adverse events or pain associated with the HO. Moreover, patients were not experiencing statistically different range of motion as a result of the formation in comparison to remaining population except in the 2 patients with Class IV. HO formation in this study does not appear to be device-related but more a result of surgical technique. The use of NSAIDs post-operatively may significantly reduce the formation of HO.



Heterotopic Ossification at the Index Level after ProDisc -C Surgery: What is the Clinical Relevance?

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BACKGROUND CONTEXT: Heterotopic ossification (HO) has been defined as the abnormal formation of new bone at joints and within soft tissue. HO is a multi-factorial bodily response. It has been reported after trauma, surgery, and peripheral events. Causal theories of HO include genetic predisposition, muscle and tissue damage, surgical implantation technique, and peri-operative measures. The incidence of HO following cervical total disc replacement (TDR) should be interpreted based on a classification system of clinical and motion relevance, as proposed below, rather than the current radiograph based system.

PURPOSE: The purpose of this study was to retrospectively investigate the clinical relevance of HO in patients treated with the ProDisc-C TDR and establish a classification system based on these clinical findings.

STUDY DESIGN/ SETTING: Data from a prospective, consecutive case series.

PATIENT SAMPLE: 117 patients treated with the ProDisc-C TDR were retrospectively evaluated at 2–5 years post-surgery.

OUTCOME MEASURES: Radiography determined the presence of anterior ossification. Patients could be classified without a CT scan or MRI. HO was assessed according to a clinical classification system: C0–ossification present but not clinically relevant; C1–ossification present and clinically relevant, based on no improvement in Neck Disability Index (NDI) scores; M0– ossification present but not motion relevant; M1–ossification present and motion relevant, based on Range of Motion (ROM). Patients were rated using a combination of these four classifications. Those patients classified as having C1 ossification had significant clinical consequences.

METHODS: Patients were assessed pre-operatively and post-operatively at 6 weeks, 3, 6, 12, 24, 36, 48, and 60 months.

RESULTS: At 2–5 years post-surgery, radiographic evaluation of Pro- Disc -C patients identified 9.4% as having HO. The mean flexion/extension (F/E) ROM for HO patients was comparable to the mean F/E ROM for the entire group of patients. Of these HO patients, none were classified as C1 based on their NDI scores. Although HO may exist on radiographs, the clinical relevance of such findings in and of themselves is inconsequential. Patients not classified as C1 were not experiencing greater pain associated with HO, nor was there a statistically different range of motion as a result of the HO formation in comparison to the remaining patient population.

CONCLUSIONS: HO formation following cervical TDR appears to be a result of surgical technique. HO may be prevented by peri-operative interventions, including: using pharmacological agents such as nonsteroidal anti-inflammatory drugs (e.g., Indomethacin) or Diphosphonates; irrigating and suctioning the surgical site to remove bone fragments; reducing retraction forces on the longus colli muscle to lessen soft tissue trauma; reducing bone surface by using the largest appropriate device footprint; cutting off the highly metabolically active rim of the vertebral body; using bone wax to seal open bony surfaces; and by positioning the center of rotation at least to the 50% margin (area of equilibrium).