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artificial disc

Clinical Update

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Heterotopic Ossification

Update on clinical evidence

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 the main contributing factors include genetic predisposition and surgical technique. The latter can be successfully mitigated through techniques described in this bulletin.

Prevalence of HO in cervical arthroplasty

Some level of post-operative HO is commonly reported in cervical TDR publications (see Fig. 1). Typically, the degree of HO is categorized by qualitative radiographic analysis on a 5-point scale (0-IV). While classification definitions vary, the highest level (Class IV) is generally reserved for bridging bone that effectively stops motion at the segment. Class III HO is generally defined as a partial reduction in motion due to HO formation. A representative sample of published data on the prevalence of categorized HO is presented as follows:

Fig. 1 Literature Summary

Author	Study	Levels	Follow-up time	Class III HOs	Class IV HOs
Mehren, C. et al	Heterotopic Ossification in Total Cervical Artificial Disc Replacement. (ProDisc-C) Spine, Vol. 31, No. 24, 2006.	77	12 mo.	10.4%	9.1%
Murrey, D. et al	Results of the prospective, randomized, controlled multicenter FDA IDE study of the ProDisc-C vs. anterior discectomy and fusion for the treatment of 1-level symptomatic cervical disc disease. The Spine Journal, 2008.	103	24 mo.	not reported	2.9% (bridging bone)
Suchomel, P. et al	Clinical results and development of heterotopic ossification in total cervical disc replacement during a 4 year follow-up. (ProDisc-C) Eur Spine J, 2010, 19:307-315	60	24 mo.	14%	19%
Beaurain, J. et al	Intermediate clinical and radiological results of cervical TDR (Mobi-C) with up to 2 years follow-up. Eur Spine J, 5/12/09	85	24 mo.	3.9%	7.9%
Quan, G. et al	Eight-Year Clinical & Radiological Follow-up of the Bryan Cervical Disc Arthroplasty. Spine, Vol. 36 No. 8, 2011	27	96 mo.	11%	22%
Combined M6-C Pilot & Registry: Germany, USA & Mexico *(Independent qualitative analysis by Medical Metrics, Houston, TX, USA)*		122	24 mo.	14.6%	4.1%

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Recommended clinical practices to minimize HO

Surgical technique and post-operative care are important determinants of post-operative HO formation. Key factors appear to be related to bleeding of exposed bone and post-surgical inflammatory response. HO may be reduced by adopting these techniques:

- When preparing the disc space for implant, avoid over-working the vertebral endplates. Keep as much cortical bone intact as possible.
- After use of the trial and chisel, copiously irrigate the surgical field.
- Select a disc footprint size that will maximize endplate coverage, particularly anterior to posterior. See the M6-C Surgical Technique Manual for more detail on proper endplate size selection.
- After implantation, use bone wax to cover bleeding bone on the anterior margins of the vertebral body.
- The use of NSAIDS for up to 6 weeks post-operatively is believed to contribute positively to minimizing HO. See references below for discussion of clinical evidence.

Conclusion

Observed occurrences of HO in cervical disc arthroplasty are common in published literature. Variations in classification criteria, patient predisposition, endplate coverage and surgical technique are presumably the main sources of variation in prevalence. The M6-C disc has a low Class IV “bridging” HO rate, and the combined Class III and IV rates are comparable to that of other discs studied. Clinical experience points to the use of specific surgical techniques and post-operative care that can minimize the amount of HO observed after any cervical arthroplasty procedure. This should lead to lower HO rates as these lessons are put into practice.

References

1 Reyes-Sanchez, A. et al. Initial clinical experience with a next-generation artificial disc for the treatment of symptomatic degenerative cervical radiculopathy. *SAS*, March 2010, Vol. 4., No. 1

2 Mehren, C. et al. Heterotopic ossification in total cervical artificial disc replacement. *Spine*, 2006, 31:2802-6

3 Murrey, D. et al. Results of the prospective, randomized controlled multicenter FDA IDE study of the ProDisc-C total disc replacement versus anterior discectomy and fusion for the treatment of 1-level symptomatic cervical disc disease. *The Spine Journal*, 2009. Vol. 9, Issue 4.

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