

22. Lumbar Nerve Root Injury with BMP2

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BACKGROUND CONTEXT: Temporary nerve root injury is the most frequent complication of Minimally Invasive Transforaminal Lumbar Interbody Fusion (MITLIF). BMP2 has been reported to cause post operative nerve root problems.

PURPOSE: Study nerve root injury rates from MITLIF comparing interbody BMP2 to silicated calcium phosphate (SCP).

STUDY DESIGN/SETTING: Prospective study of 504 procedures in 483 patients undergoing single level MITLIF with unilateral pedicle screw fixation (most with unilateral posterior-lateral fusion). Sequential groups using interbody BMP2 or SCP were evaluated.

PATIENT SAMPLES: 411 procedures using BMP2: 212 males, 199 females, ages 18 to 83, mean age 54. 93 procedures using SCP: 41 males, 52 females, ages 17 to 84, mean age 56.

OUTCOME MEASURES: 1. Clinical evaluation of new post operative pain and weakness. 2. Pre- and post-operative VAS for upper and lower leg pain.

METHODS: 1. Determine incidence of new nerve root injury (pain or weakness) using interbody BMP2 versus SCP. 2. Evaluate gender effect. 3. Compare pre- and post-op VAS scores for leg pain using interbody BMP2 versus SCP.

RESULTS:

	BMP 2			SCP		
	Group	Men	Women	Group	Men	Women
Total	27%	14%	41%	25%	19%	29%
Pain	11%	8.50%	14%	5.40%	2.40%	7.70%
Weakness	16%	5.70%	27%	19%	17%	21%

Rate of Nerve Root Injury

	BMP 2 (n=319)		SCP (n=85)	
	Upper Leg	Lower Leg	Upper Leg	Lower Leg
Pre op	5.2	4	5.5	4.3
6-12 Weeks	1.1	1.2	0.7	0.8
% Reduction	79%	70%	87%	81%

VAS Scores-Leg Pain

CONCLUSIONS: 1. Incidence of new post-operative leg pain using interbody BMP2 is twice that of SCP. 2. Females have significantly higher rates of nerve root injury when using BMP2 compared to males (both pain and weakness). 3. Post-operative VAS scores at 6-12 weeks for upper and lower leg pain are significantly lower using interbody SCP versus BMP2. 4. Reduction in pre-operative VAS scores is significantly greater using SCP versus BMP2.

FDA DEVICE/DRUG STATUS: BMP-2: Not approved for this indication; SCP: Not approved for this indication.