

National Institute for Health and Clinical Excellence

Clinical guideline: Hip Fracture

PRE-PUBLICATION CHECK ERROR TABLE

Organisation	Order number	Section number in FULL guideline	Page number	ERROR REPORT	Response
AMGEN	1	GENERAL COMMENT		TA204 was a recent appraisal conducted by NICE related to a new cost-effective option for the treatment of osteoporosis, for clinicians and patients. We strongly feel, therefore, that any omission of reference to this appraisal would prevent representation of a holistic picture of current available treatments for osteoporosis.	Thank you for your comment. TA204 has been added to the list of related NICE guidance.
AMGEN	2	2.6	13	The full guideline is factually incorrect as it fails to list TA204 Denosumab for the prevention of osteoporotic fractures in postmenopausal women as related NICE Health Technology Appraisals, despite this being both relevant and implemented before the release of this clinical guideline.	Thank you for your comment. TA204 has been added to the list of related NICE guidance.
AMGEN	3	2.6	14	There is a factual inaccuracy in the listing of the NICE osteoporosis clinical guideline, which has been suspended and will be replaced by a short clinical guideline on fracture risk assessment.	Thank you for your comment. This has been amended to reflect the new title of the short clinical guideline.
AMGEN	4	12.1	146	The references supporting available guidance for secondary prevention of fracture are not completely accurate as they include TA160 (primary prevention of fracture, reference 234) instead of TA204 (reference 236, which incorporates secondary prevention of fracture). The referencing should therefore be amended to correct this inaccuracy: "Secondary prevention of fracture by means of the assessment and management of both osteoporosis ^{235,236} "	Thank you for your comment. A reference to TA204 has been inserted here.
AMGEN	5	12.2.3	162	As in the above point, the referencing regarding guidance on secondary prevention of fractures is incorrect and should instead read: "the programmes in	Thank you for your comment. A reference to TA204 has been inserted here.

				place for the secondary prevention of fracture by means of the assessment and treatment of osteoporosis and risk of falling (see NICE Clinical Guideline 21 & Technology Appraisal 161” 227,235 236”	
AMGEN	6	13.10.1	216	As in the first point, this is inaccurate as it fails to list TA204 as related published NICE guidance.	Thank you for your comment. We are not able to make changes to the scope at this stage, but TA204 has been added to the list of related NICE guidance in the guideline.
AMGEN	7	13.10.2	217	As in the second point, the osteoporosis clinical guidelines have been suspended, and this should instead refer to the short clinical guideline on fracture risk assessment.	Thank you for your comment. We are not able to make changes to the scope at this stage, but the list in the guideline has been amended to reflect the new title of the short guideline.
RCGP	8			The NICE method team responses seem very reasonable Henry Smithson	Thank you for your comment.
Johnson and Johnson Medical	9	Section 10.4 Use of cement in arthroplasty lines 4,5,6	Page 114	This following statement on page 114, section 10.4, lines 4,5 and 6 implies that there is a difference in clinical outcome between cemented and uncemented arthroplasty; <i>“Thus a component fixed with cement may be more secure resulting in less pain after surgery and decreased need for surgical revision due to loosening of the prosthesis.”</i> Yet in section 10.4.3 on page 121/122, a separate statement contradicts the initial implication and states that as there is no clinical difference with cemented and cementless designs, cemented implants should be used as analysis shows that they <i>cost less</i> than cementless designs. <i>”As the clinical evidence did not show any advantage of uncemented over cemented arthroplasty in the newer design, and as the cost of new designs of cemented implants was shown to be lower than that of uncemented implants, the GDG agreed to consider cemented implants cost-effective for hip fracture patients”</i>	Thank you for your comment. We do not consider this to be a comment on the factual accuracy of the guideline.
Johnson and Johnson	10	Appendix H Section 20.7.12, lines	Page 604-608	There is no direct evidence comparing the use of cemented and uncemented total hip replacement, therefore NICE have used Figved ¹ which examines a	Thank you for your comment. We do not consider this to be a comment on the factual accuracy of the guideline.

Medical		24 onwards		<p>relatively small cohort of 220 patients as a reference point for two key elements of the costs analysis; LOS and re-operation. However, this in fact means that the difference in cost between cemented and cementless is largely driven by two non significant clinical outcomes:</p> <ul style="list-style-type: none"> • LOS: it has been factored in that cemented arthroplasty has a shorter length of stay compared with cementless. This is based on the Figved¹ study of 220 patients. The mean LOS was 7.8 days for the cemented group and 8.4 days for the uncemented group ($p < 0.52$) • Re-operation rates: The difference calculated in the cost of re-operations is also from Figved. The reoperation rate for cemented and cementless was 6.3% and 7.4% respectively ($p = 0.73$) <p>Including these non significant clinical parameters as economic drivers in the cost analysis is inappropriate and should be excluded. If these two factors were removed, cementless arthroplasty <u>would in fact be cheaper.</u> (See table 1 below on page 2)</p> <p>References (1) Figved W, Opland V et al. Cemented versus Uncemented Hemiarthroplasty for Displaced Femoral Neck Fractures. <i>Clin Orthop Relat Res</i> (2009) 467:2426-2435</p>	
Johnson and Johnson Medical	11	Appendix G Line 6 Figure G-71 and Figure G-72	Page 488	<p>There appears to be a mistake in the Forest plot labels E.g. Harris hip score should favour Uncemented at 79.8 but is plotted as favouring cemented.</p>	<p>Thank you for your comment. Figure G-72 has been amended. The label for Figure G-71 states that this outcome is the number of patients with a Barthel score of less than 19 at 12 months. Therefore the axis labelling is correct as higher number indicates a poorer</p>

					outcome.
Stryker UK	12	10.6.1.4	129	<p>The recommendation made is based on the assumption that Intra Medullary devices have a higher re-operation rate due to intra/post operative fractures. The Bahndar metha analysis attached disproves this theory. The Bahndar Report also supports the impact of better postoperative outcome and the cost benefit gained from resources ie reduced length of stay – which should be considered when looking at cost effectiveness.</p> <p>We therefore believe the recommendation: Use extramedullary implants such as a sliding hip screw in preference to an intramedullary nail in patients with trochanteric fractures above and including the lesser trochanter (AO classification types A1 and A2). Should be amended to consider all the available evidence..</p> <p>Abstract below:</p>	<p>Thank you for your comment. We do not consider this to be a comment on the factual accuracy of the guideline.</p> <p>.</p>

				<p>Date: 2010-09-02 Session: Trauma - Pertrochanteric Fractures Time: 13:30-15:00 Room: Congress Hall</p> <p>Abstract number: 24444 FUNCTIONAL OUTCOMES FOLLOWING INTRAMEDULLARY NAIL VERSUS CONVENTIONAL SLIDING HIP SCREWS FOR PERTROCHANTERIC HIP FRACTURES: A PILOT MULTICENTER, RANDOMIZED CONTROLLED TRIAL Mohit BHANDARI¹, Alicja BOJAN², Carl EKHOLM², Ole BRINK³, Anita SHEILA SPRAGUE¹, Nasir HUSSAIN¹, Anders JÖNSSON⁵ ¹Division of Orthopaedic Surgery, Hamilton, Ontario (CANADA), ²Department of Orthopaedic Surgery, Göteborg (SWEDEN), ³Department of Orthopaedic Surgery, Copenhagen (DENMARK), ⁵Global Medical Science, Schönkirchen (GERMANY)</p> <p>Purpose: The popularity of intramedullary nails (IMN) for trochanteric hip fractures has grown substantially with little supportive evidence that IMN are superior to conventional sliding hip screws (SHS). Methods: We conducted a multi-center, randomized trial including 3 clinical sites across Sweden, Denmark, and Germany. We randomized 85 elderly patients with stable and unstable trochanteric hip fractures to either SHS or an IMN. The primary outcome, revision surgery, was adjudicated at one year. Secondary functional outcomes included the Parker Mobility Score (PMS), the Merle D'Aubigne Score and the Euroqol-5D. Results: 85 patients were enrolled. Fifteen patients died prior to the one year follow-up. In both treatment groups, patients did not differ in age, gender and fracture type. The revision risk was 11.6% (8/69) and did not differ significantly between groups (SHS: 3). Patients treated with IMN had significantly higher Merle D'Aubigne scores at 6 (p=0.01) and 12 months (p=0.05). Gamma3 nails had significantly higher scores in the Parker mobility score at 6 (p=0.08) and 12 months (p=0.056). Non-significant differences were identified in the Euroqol-5D life measures; however, the Gamma3 nailed tended to higher scores than the sliding hip screw. Conclusion: Our findings of early functional gains without increase in risk of revision surgery support the increased popularity of IMN for the management of trochanteric hip fractures in elderly patients.</p>	
Stryker UK	13	10.6.1.5	129	<p>The recommendation made is based on the assumption that Intra Medullary devices have a higher re-operation rate due to intra/post operative fractures. The Bahndar metha analysis attached disproves this theory. The Bahndar Report also supports the impact of better postoperative outcome and the cost benefit</p>	<p>Thank you for your comment. We do not consider this to be a comment on the factual accuracy of the guideline.</p>

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FUNCTIONAL OUTCOMES FOLLOWING INTRAMEDULLARY NAIL VERSUS CONVENTIONAL SLIDING HIP SCREWS FOR PERTROCHANTERIC HIP FRACTURES: A PILOT MULTICENTER, RANDOMIZED CONTROLLED TRIAL

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Purpose: The popularity of intramedullary nails (IMN) for trochanteric hip fractures has grown substantially with little supportive evidence that IMN are superior to conventional sliding hip screws (SHS). Methods: We conducted a multi-center, randomized trial including 3 clinical sites across Sweden, Denmark, and Germany. We randomized 85 elderly patients with stable and unstable trochanteric hip fractures to either SHS or an IMN. The primary outcome, revision surgery, was adjudicated at one year. Secondary functional outcomes included the Parker Mobility Score (PMS), the Merle D'Aubigne Score and the Euroqol-5D. Results: 85 patients were enrolled. Fifteen patients died prior to the one year follow-up. In both treatment groups, patients did not differ in age, gender and fracture type. The revision risk was 11.6% (8/69) and did not differ significantly between groups (p=0.3). Patients treated with IMN had significantly higher Merle D'Aubigne scores at 6 months (p=0.01) and 12 months (p=0.05). Gamma3 nails had significantly higher scores in the Parker mobility score at 6 months (p=0.08) and 12 months (p=0.056). Non-significant differences were identified in the Euroqol-5D life measures; however, the Gamma3 nailed tended to higher scores than the sliding hip screw. Conclusion: Our findings of early functional gains without increase in risk of revision surgery support the increased popularity of IMN for the management of trochanteric hip fractures in elderly patients.



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Table 1 Johnson and Johnson medical

Cost Categories	Patients who received cemented implants	Patients who received uncemented implants	Costs of cemented procedure <i>if insignificant factors are removed</i>	Costs of uncemented procedure <i>if insignificant factors are removed</i>
a) Implants	£383.86	£789.15	£383.86	£789.15
b) Accessories costs for cemented implants	£248.99	£0	£248.99	£0
c) LOS	£1872	£2016	N/A (<i>not significant</i>)	N/A (<i>not significant</i>)
d) Re-operations	£100.70	£118.28	N/A (<i>not significant</i>)	N/A (<i>not significant</i>)
e) Incremental theatre costs for cemented group	£254.2	£0	£254.2	£0
Total Costs	£2859.75	£2923.43	£887.05	£789.15