Author's response to reviews

Title: 3066 consecutive Gamma Nails. 12 years experience at a single centre.

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Author's response to reviews: see over
Re: 3066 consecutive Gamma Nails. 12 years experience at a single centre.

To the Editor and the Reviewers

Thank you for valuable comments and corrections.

Reviewer 1

**Major compulsory revisions**

1. We have re-built the rationale and the construction of the Background. The focus lies in the investigation of complications after treatment of proximal femoral shaft fractures with Gamma Nails.
2. Our study focuses on the evaluation of the Gamma Nail performance. We therefore included every patient treated with this implant. It is a consecutive cohort of patients where no patient was excluded. The only specific inclusion criterion was the treatment with the Gamma Nail, which also was the only method used for the trochanteric fractures at this hospital during the study period. Please, see Par 1 in the Methods.
3. We discuss the lower complication rates in the Discussion, please, see page 15, Par 1. The other “take home message is: “We attribute the low rate of the postoperative femoral shaft fractures in this report to strict adherence to the original surgical technique at this study centre.” Discussion, page 15.
4. We do not claim that the Gamma Nail has been ”misrepresented” in the literature. Rather we highlight the complications with use of the Gamma Nail and the controversies around it and similar implants - such has the wide-spread use despite a meagre scientific foundation. Our conclusion is that the strict adherence to the surgical technique, which was developed at the study centre (CTO) and the design improvement reduces the complication rate, which is in accordance with the work of Bhandari et al [1].
5. In our study, the distribution for the variable “age” is significantly skewed and not normally distributed (p<0.001, tested with Shapiro-Wilk test and Skewness tests). This fact has not been presented correctly in the primary manuscript. Instead of presenting the mean value, standard deviation and confidence intervals, our statistician recommends presenting the median, range and interquartile ranges for the variable “age” because of this skewed distribution. As an example for further explanation of this issue, please find attached the overall analysis of the variable “age” (n=3066).
Gothenburg, 16th March, 2010

Statistical significance for all tests was set at p-values less than 0.05. Missing p-values have been added. For normal distributed continuous variables, mean values, standard deviations and confidence intervals are shown. For non-normal distributed continuous variables, median, range and interquartile ranges (IQR) are displayed. The statements "equal" and "no difference" have been corrected and related test statistics have been added.

### Minor Essential Revisions

1. The major style and diction problems have been corrected, also bearing in mind that the reviewer 2 found the style acceptable.
2. We have defined and described the fractures in the Methods with help of AO/ASIF classification system. We have included the basocervical fractures.
3. Background
   - Paragraph 1: more references have been added
   - Par 2: “Debate” has been explained
   - Par 3: The Background has been re-built according to reviewer’s recommendation. Please, see 2 in Major Compulsory Revisions
   - Par 4 and 5: The Background has been re-built. The differences between nails has not been explained in detail in this work as they can be easily retrieved from other publications [2]
4. Methods
   - Par 1: “the standard procedure” has been removed from text since the explanation of OP technique can be extracted from OP manuals. In our opinion the other Gamma Nails do not have to be excluded, since they are part of a consecutive

### Descriptives

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### Tests of Normality

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a. Lilliefors Significance Correction

Statistical significance for all tests was set at p-values less than 0.05. Missing p-values have been added. For normal distributed continuous variables, mean values, standard deviations and confidence intervals are shown. For non-normal distributed continuous variables, median, range and interquartile ranges (IQR) are displayed. The statements "equal" and "no difference" have been corrected and related test statistics have been added.
Gothenburg, 16th March, 2010

patient group and the nails do not differ fundamentally in their design (i.e. steel and titanium as material)

• Par 2: The information on surgical experience was not retrieved during data collection.

• Par 3: “equally common” corrected

• Page 7, Par 2: “Exceptions were made…” corrected

• Page 7, Par 4: Reduction criteria have been defined more explicit.

• Page 8, Par 2: corrected

• Statistics: “SPSS data base” has been replaced with “the case report form and the corresponding variables were uniquely generated for our patient population…” "Comparative analysis was performed by using the Chi-Square test for nominal and ordinal variables by evaluating frequencies within the groups with the method of cross tabulation.” Statistical significance for all tests was set at p-values less than 0.05. For normal distributed continuous variables, mean values, standard deviations and confidence intervals are shown. For non-normal distributed continuous variables, median, range and interquartile ranges (IQR) are displayed beside the mean value, which is shown in brackets.” Please, see also 5 in Major Compulsory Revisions

• Only one evaluator of radiographs: discussed according reviewer’s recommendation, par 1, page 19.

5. Results

• Please, see point 5 in Major Compulsory Revisions, we also explain in manuscript: “… median age 81 years, ranging from 14 to 106 years and with an IQR of 16 years (mean age 77 years). In the overall patient population as well as in the subgroups, the variable age shows always a significantly skewed distribution (p<0.001).”

• Please, see page 7, Par 2. The main outcome of the study are implant related complications which bring the patient back to the hospital. We also discuss: “Only 1980 (64.6%) patients had at least one follow-up entry in our data base.” see page 18, par 2.

• A p-value to the statement “equally common” has been added. “Left- and right-sided fractures were equally common (p=0.136)”

• Addition of p-value. “The fracture aetiology did not change during the study period. Males in all age groups were more likely than females to sustain a fracture from high-energy trauma (traffic accident or fall from a height) 21.3% vs. 2.3% (p<0.001).”

• “fracture incidence …” has been corrected

• “compound fracture” has been replaced with “open fracture”

• The demographics section has been re-structured

• In this section we wanted to emphasise a different indication for the Long Gamma Nail with more complex fractures in younger patients and clarify the reason for its use.

• Percentages representing opinions: In this retrospective data set the information about the nail insertion characteristics were retrieved from surgical notes and these comments were not mandatory, rather subjective evaluation by the attending surgeon.
6. Discussion
  • Paragraph 2: “the incidence” and “no difference” have been corrected as recommended; we present the important loss to follow up as a limitation in the discussion.
  • We were not able to evaluate the influence of surgical experience on the outcome; nevertheless, we believe that the statement that strict adherence to the surgical technique results in low complication rate is correct. We wanted to emphasise the importance of the CTO as a hospital developing and propagating the right OP technique.
  • The data have been presented in the Table 2 in the Results part.

Discretionary revisions
  1. We believe that the title is adherent with the content and purpose of the study: the outcome performance of the consecutive patients treated with Gamma Nails with the focus on demographics and fracture site complications.


Reviewer 2

We have corrected the AO/ASIF classification 32-A in Table 3.

Yours sincerely,

Alicja Bojan, MD