Reviewer’s report

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

Version: 2 Date: 18 November 2009

Reviewer: Jaimo Ahn

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This study is a retrospective series of 3066 cases of trochanteric hip fractures treated at one major trauma center with a single type of device from a single manufacturer. This is the largest series for this type of device and the authors are to be commended for what amounts to a tremendous undertaking. However, the specific goals of the study and its implications are unclear. The data from such a collection of cases will be valuable and will indeed add to the literature—when the current major limitations are overcome.

- Major Compulsory Revisions
1. The central thesis of the study is unclear making the results and conclusions difficult to evaluate

The authors state they "decided to perform a thorough investigation" but to what end? Is their goal to report the overall performance of the technique, to investigate the complications, to investigate post-operative femur fractures, all of the forementioned? This needs to be defined and clarified as it is not explicitly stated. The Background needs to build a rationale and provide evidence for the formulation of either a hypothesis or specified goal(s).

2. The actual patient data set is unclear

Authors state that 3066 patients between 1990-2002 were evaluated. Does this mean every single patient during this period with a trochanteric fracture was treated only with a Gamma nail and no other device or manufacturer’s product? Or is this a collection of only the patients that received a Gamma. Were there specific inclusion and exclusion criteria applied? How were patients dropped from the cohort due to incomplete data? We do not need a complete accounting of the patient cohort but, in order for it to be evaluated and understood by the reader, it must be clear.

3. The overall relevance is unclear

As the authors state, we have new generations of nails with lower complication rates reported in the literature (other authors, for this particular implant and others). Therefore, the results of this paper will unlikely influence the fixation of future fractures. That said, it would be important to know that the many patients already fixed with the Gamma can expect, for instance, a low rate of future periprosthetic fractures. The authors are advised to discuss this type of relevance to emphasize the utility of their study.

4. Potential for bias
As it stands, the overall emphasis of the paper appears to be biased toward providing evidence that the Gamma has been specifically misrepresented in the literature. I cannot assess whether it has been so misrepresented but the fact that the authors of the paper are closely aligned with the device manufacturer will not be lost on the general reader. The authors are advised to formulate specific goals and questions that will provide useful information for those who use Gamma nails or other wise (and with such a large cohort, it is difficult to imagine that such information will not be gleaned).

5. Statistical methods

Although the authors state their statistical methods, they do not provide sufficient data in this regard. This includes no use of confidence intervals, no reporting of standard deviations, and minimal reporting of p values; all these data need to be reported. Also, authors are cautioned against stating that comparison values are "equal" or there is "no difference" unless they specifically tested for equivalence; instead they should state that the difference was not statistically significant or that no statistically significant difference was found.

- Minor Essential Revisions

1. The authors are advised to obtain additional editing for style, diction etc. The essential message gets across but there is awkwardness of usage.

2. "Trochanteric" fracture needs to be more clearly defined esp due to the different terms used internationally regarding these fractures. Perhaps "extraarticular proximal femur and subtrochanteric fractures including basicervical (included?), intertrochanteric and pertrochanteric fractures," "combination fractures that included a shaft extension or separate shaft component were included; isolated greater and lesser trochanter fractures were not included."

3. Background

Paragraph 1 - more references are needed for the perceived advantages.

Par 2 - please explain what the debate/s is/are.

Par 3 - "We therefore decide to perform..." needs a more compelling lead up; that is, the prior two paragraphs need to make the investigation compelling and the nature of the investigation needs to be more explicit. Also, the last part of the paragraph needs to be clarified and moved to methods: are these all patients with trochanteric fractures presenting to the trauma center, just the ones treated with Gamma, what are the inclusion and exclusion criteria etc.

Par 4, 5 - while the history of the development of the Gamma is of interest, how does it relate to the central thesis of the paper; authors need to link all background material in a compelling way to their main goals. Also, the differences between the nails and how they relate to the goals of the investigation are of interest and should be explained.

4. Methods

Par 1 - explain "the standard procedure"; consider excluding the other nails unless they add to the analysis; otherwise they do not add substantially to the
total N and serve as a distraction

Par 2 - procedures were performed by senior surgeons and those in training; this is an important point and may be a significant covariate of complications; if all of the technical complications occurred from surgeries performed by training surgeons, that is of great importance! Authors should attempt to extract this information and if not possible, discuss in the limitations.

Par 3 - "equally common" should not be used unless this was statistically evaluated.

Page 7, Par 2 - "Exceptions were made...in another institutions" is unclear and should be clarified.

Page 7, Par 4 - the criteria for malreduction are unclear. Authors describe displacement (and not angulation, for instance) as the only criteria on AP and only angulation on the Lateral. Please provide more explicit criteria.

Page 8, Par 2 - perhaps the authors meant to say that operating time and blood loss records were incomplete or irretrievable.

Statistics - please clarify what it means for the SPSS database to be "uniquely designed" for the study. Please clarify statement regarding missing data. Did the authors mean to state that distribution ratios for categorical variables were evaluated with contingency table analysis using the Chi-square statistic? Also, did the authors mean to state that statistical significance was set at p value less than 0.05 and that 95% confidence intervals are shown when appropriate?

Having only 1 evaluator of radiographs does eliminate interobserver differences but it also make the data more influenced by the errors of that one reader. Furthermore, intraobserver errors are not eliminated, rather they may be amplified.

5. Results

Where means are presented, standard deviations should also be shown.

Average followup time should be presented.

The term "equally common" should not be used without statistical basis.

The statement "fracture incidence increased with age..." is not true incidence as the denominator per time is not known.

The term "compound fracture" should be replaced with "open fracture"

The first few paragraphs present some interesting demographics but the underlying organization or theme needs to be clarified.

Please make sure that data presented fit within the authors’ specific framework; for instance, the age and energy/mechanism stratified by nail type seems out of context and it is unclear how this should be used by the reader.

Please temper the use of percentages representing opinions (difficult nail insertion, why distal locking was not performed, intra-operative problems) gleaned retrospectively from patient charts; unless the recording of such data is mandatory to the records, it is highly prone to bias of numerous types. The surgeon may not have noted it for various reasons or it could have simply been
missed by the extractor of data.

6. Discussion

In general, authors are suggested to present their conclusions based on their own data and that in the literature in line with the goals presented in the Background.

Paragraph 2 - as the authors state, the complication rate (not incidence) does appear to be low; however, because the reader is not given specific data regarding followup (% loss to followup, ave followup frequency, ave followup time), it is difficult to know the true fracture rate or to accurately compare stratified complications. Again, "no difference" should only be used with proper statistical support.

One theme the authors present is the idea of better results with better technique. While this is generally accepted at face value by most practitioners, the authors are cautioned against making firm statements without reasonable data to support them. For instance, the authors state that "more surgical experience" could control intraoperative problems. Yet, they were not able to evaluate this in their data set. Indeed, this information, if it could be extracted from this cohort, would be of great interest. Also, the authors say that the low "incidence" (should be "rate") of post operative fractures is due to strict adherence to surgical technique. While this *may* be true and while the authors are encouraged to suggest opinion-based connections regarding their conclusions, such statements are virtually impossible for the reader to evaluate even at a logical or intellectual level.

Page 16 - data should be presented in Result and may be referred to in Discussion.

- Discretionary Revisions
  1. The title would be more useful if it conveyed the purpose of the study

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests