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Letter

# The need for better analysis of observational studies in orthopedics

A retrospective study of elbow fractures in children

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## Abstract

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were used to compare traditional least-squares regression analysis with a 2-level model

with interactions.

Results

Results We found that 25% of the variance in outcome could be attributed to between-surgeon variance. We identified an interaction between the surgeons' experience and

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the severity of the fractures that influenced the conclusions. The variable "number of

pins" was not significant in the 2-level model ( $p = 0.07$ ), while the ordinary least-

squares analysis gave a result that was statistically significant ( $p = 0.01$ ).

Interpretation Researchers should consider the need for a 2-level model and the presence of interactions. Standard statistical methods might lead to wrong conclusions.

Supracondylar humerus fractures are the most common elbow injuries in children who require surgery. Percutaneous pinning has become the method of choice in most clinics, and severe complications are rare (Otsuka and Kasser [1997](#)). Recent reports have suggested that delay of surgery until the next day is safe (Iyengar et al. [1999](#), Mehlman et al. [2001](#), Leet et al. [2002](#), Gupta et al. [2004](#)). However, vascular injuries and compartment syndromes still occur (Ramachandran et al. [2008](#)), and some authors recommend treating these fractures as early as possible (Walmsley et al. [2006](#)). The statistical methods employed in these publications are t-test, the chi-square test, and simple and multiple regression analyses. These methods require the fundamental assumption that the observed outcomes are independent, which implies that none of

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likely to be more similar than if they were not. Ignoring such correlations may lead to underestimation of standard errors, increasing the risk of committing a type-i error with the conclusion that a variable is statistically significant when it is not. A multilevel approach (also called hierarchical modeling) accounts for potential correlations by modeling intercepts and regression coefficients as random. The intraclass correlation coefficient (ICC) expresses the amount of dependency among observations and is calculated to decide whether a multilevel analysis is appropriate. The ICC can take values from 0 to 1. A non-zero value of ICC implies that the observations are not uncorrelated and that there is a need for multilevel modeling.

Furthermore, orthopedic researchers should consider the existence of interaction, also known as effect modification (Moyé [2006](#)). An interaction is defined as a factor that modifies the independent factor under study. This is analytically more complex than simple confounding. A confounder has the same effect on outcome for all values of the other independent variables studied. Interactions reflect that the effect of one variable depends on the values of one or more other variables. For example, the influence of the surgeon's experience on outcome could be stronger for severe fractures than for less complicated ones. In such cases, a statistical model with interactions should be tested.

Here we describe to the orthopedic community the concept of multilevel modeling and interactions as necessary statistical tools in observational studies. We show that the conventional statistical methods currently employed in retrospective reports may yield misleading results.

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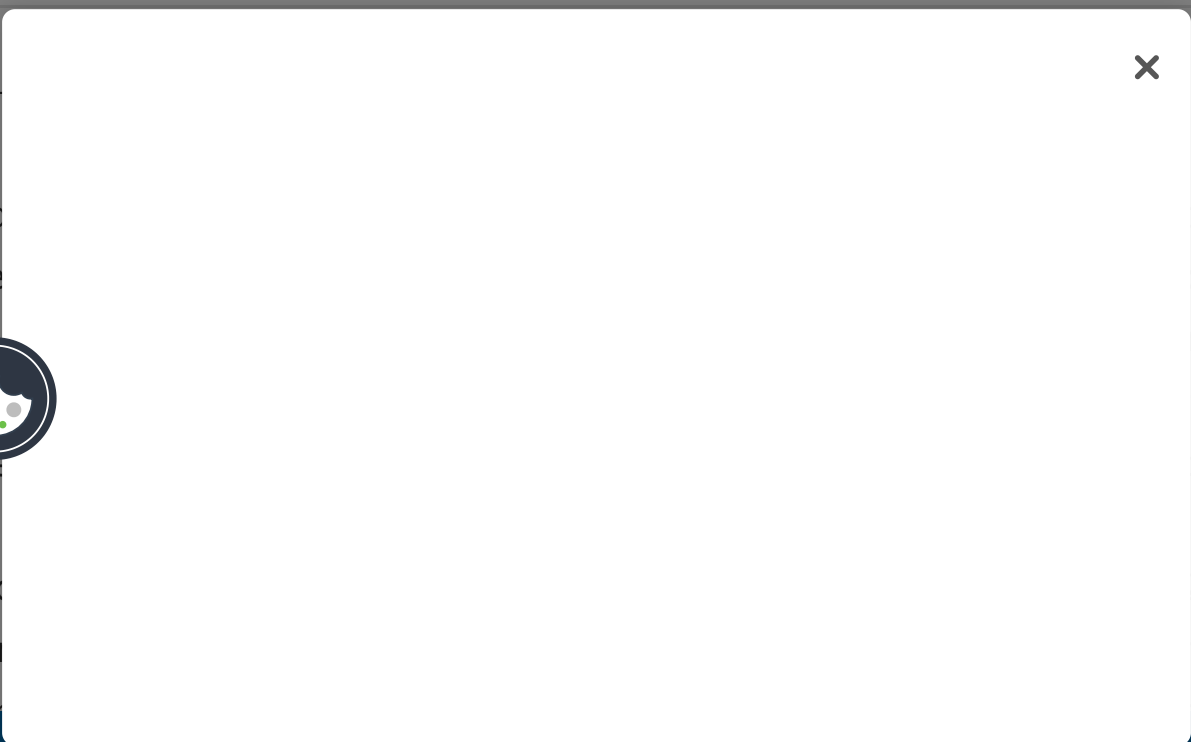
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Surgeons were classified in two groups according to their level of experience: consultants and residents. If two surgeons performed an operation together, the most experienced was chosen as being responsible for treatment of that fracture.

Discussion

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References

## Table 1. Demographic and fracture characteristics of 112 supracondylar humerus fractures in 112 children



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### Radiographic analysis

Standard AP and lateral radiographs were used. The Gartland classification of the lateral film was recorded by PHR (Gartland [1959](#)). This classification has good intra- and interobserver reliability (Barton et al. [2001](#)).

### Clinical examination

All patients were given written information about the study and were invited to attend a follow-up clinic. 3 patients had moved abroad or to a different part of the country. 9 patients were lost to follow-up, and 22 patients refused to participate, leaving 78 patients available for clinical examination on average 4.3 (1.5–9) years after admission. The surgeon's experience was not revealed to the investigators examining the patients (PHR, EAS, and IS). The cubitus angle and range of motion were measured clinically using a goniometer. The Flynn criteria (Flynn et al. [1974](#)) were used to assess the

functionally and the patients the help of their parents a VAS score where zero was uninjured to the

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Initially, an unconditional model (one without explanatory variables) was estimated to calculate the ICC, which can be interpreted as the percentage of variation in VAS score that could be explained by the surgeon level.

#### Discussion

A hierarchical linear modeling approach with 2 levels (patient and surgeon) was chosen to model the main outcome variable VAS score. Even though the VAS score was a highly skewed variable, a 2-level linear model (Fitzmaurice et al. [2004](#)) was estimated. Simple analyses were then used to assess the association between the outcome variable and the main predictors. 4 variables were considered to be main predictors for the VAS score. The Gartland classification and the surgeon's level of experience (either consultant or resident) were considered to be predictor variables based on the notions that more displaced fractures have more complications and that more experienced surgeons have better results. The variable night (between midnight and 8 a.m.) or day was selected based on the tendency to perform fewer operations during the night to reduce the risk of adverse outcome (Rothschild et al. [2009](#)). There is no consensus on the number of pins needed for adequate fixation. Some authors recommend the use of 3 pins in unstable fractures (Gordon et al. [2001](#), Vlahovic and Bumci [2002](#)). We therefore included the number of pins as a predictor variable in the model. Time to surgery, preoperative neurovascular status, age, and sex were considered as confounders.

Technically, to account for interactions a new variable, which is the product of 2 (usually) independent variables, is introduced into the model. One should not try out all possible interactions since this increases the risk of spurious results. Thus, when

building a model, one should be cautious about the number of interactions to include. In this study, we included the interaction between the surgeon's level of experience and the time of surgery. This interaction was not significant, suggesting that the risk of adverse outcome is similar for consultants and residents, depending on the time of surgery. The interaction between the surgeon's level of experience and the number of pins was also not significant, suggesting that the risk of adverse outcome is similar for consultants and residents, depending on the number of pins. The interaction between the surgeon's level of experience and the number of pins was also not significant, suggesting that the risk of adverse outcome is similar for consultants and residents, depending on the number of pins.



There were no cases of permanent neurovascular injury, deep infection, or compartment syndrome. The retrospective review of the medical records of the 112 fracture patients revealed 21 postoperative complications (19%) (Table 2). Gartland 3 fractures were operated earlier and more often by consultants, and had more complications than Gartland 2 fractures.

#### References

Table 2. Postoperative complications recorded for the 112 fractures



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11 of the 78 elbows available for clinical examination had a cubitus varus malunion. The mean VAS score was lower in patients who developed cubitus varus (7.7 vs. 9.6) than in patients who had a positive carrying angle ( $p < 0.001$ , Mann-Whitney test). 20 patients had a positive Quick-DASH score (Table 3).

Table 3. Clinical outcome of 78 fractures at follow-up, mean 4.3 years after surgery



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The overall amount of variation in outcome explained by our model was 18%. By estimating that 25% of the total variance is explained by our model suggests that an overfit model would be misleadingly significant. The relationship between the explanatory variables and the outcome is not sufficient to support the model (Table 4).



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In the OLS model without interactions, there was a positive correlation between number of pins and patient satisfaction ( $p = 0.02$ ), while in the 2-level model with interaction terms included this correlation was not significant ( $p = 0.07$ ). Neither the surgeon's experience nor the severity of the fracture influenced the VAS score significantly. The combination (interaction) of the two, with marginally significant effect on the outcome ( $p = 0.05$ ), influenced the conclusions sufficiently to be included in the final model.

Although the 2-level model corrected the problem of underestimated standard errors in OLS regression, the results did not differ much in the 2 models. Only the number of pins was no longer statistically significant in the 2-level model. If we had used only a simple OLS model, we would have reported number of pins as an explanatory variable.

## Discussion

Our point is not that the last word about treatment of supracondylar fractures has been said, but that simple statistical models do not suffice. We found that the clinical outcome after pinning of displaced supracondylar humerus fractures in children is good or excellent in most cases, which is consistent with previous reports (Foad et al. [2004](#),

Devkota et al. [2015](#)). The use of a 2-level model is of function, and so, the use of a 2-level model is of treatment, and so, the use of a 2-level model is of of statisti model changed atory variab d attributed to the surg pedics must co el in nature (patient red by calculati in relatively

in published papers, so that readers can consider the clinical relevance of statistically significant results. Furthermore, findings in previous studies where an OLS model without interactions has been used—and where the conclusions have had an impact on clinical practice—should be reviewed using these statistical methods.

#### Acknowledgements

#### References

PHR initiated and designed the study, collected data, organized the follow-up clinic, examined patients, and wrote the manuscript. EAS and IS examined patients and reviewed the manuscript. JSB built the statistical models and revised the manuscript. PG contributed to the study design and to critical revision of manuscript.

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No competing interests declared.

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3. Devkota P, Khan JA, Acharya BM, Pradhan NM, Mainali LP, Singh M, Shrestha SK, Rajbhandari AP. Outcome of supracondylar fractures of the humerus in children treated by closed reduction and percutaneous pinning. JNMA J Nepal Med Assoc

2008;47(170):66-70.

References  
PubMed | Google Scholar

4. Fitzmaurice GM, Laird N, Ware J. Applied longitudinal analysis. John Wiley & Sons, 2004.

Google Scholar

5. Flynn JC, Matthews JG, Benoit RL. Blind pinning of displaced supracondylar fractures of the humerus in children. Sixteen years' experience with long-term follow-up. J Bone Joint Surg (Am) 1974;56(2):263-72.

PubMed | Web of Science ® | Google Scholar

6. Foad A, Penafort R, Saw A, Sengupta S. Comparison of two methods of percutaneous pin fixation in displaced supracondylar fractures of the humerus in children. J Orthop Surg (Hong Kong ) 2004;12(1):76-82.

PubMed | Google Scholar

7. Gartland JJ. Management of supracondylar fractures of the humerus in children. Surg Gynecol Obstet 1973;137(1):87-91.

PubMed

8. Gordon J, et al. Stability after percutaneous pinning of supracondylar fractures of the humerus in children. J Pediatr Orthop 2004;24(1):1-6.



9. Gupta A, et al. Functional delay on the humerus after supracondylar fracture.

0. Jyengar SR, Hoffinger SA, Townsend DR. Early versus delayed reduction and pinning

of type iii displaced supracondylar fractures of the humerus in children: a  
Results comparative study. J Orthop Trauma 1999;13(1):51-5.

Discussion | PubMed | Web of Science ® | Google Scholar

Acknowledgements

1. Leet AI, Frisancho J, Ebramzadeh E. Delayed treatment of type 3 supracondylar  
References humerus fractures in children. J Pediatr Orthop 2002;22(2):203-7.

PubMed | Web of Science ® | Google Scholar

2. Mehlman CT, Strub WM, Roy DR, Wall EJ, Crawford AH. The effect of surgical timing  
on the perioperative complications of treatment of supracondylar humeral fractures  
in children. J Bone Joint Surg (Am) 2001;83(3):323-7.

PubMed | Google Scholar

3. Moyé LA. Statistical reasoning in medicine. The intuitive p-value primer. Springer,  
2006.

Google Scholar

4. Office of Behavioral and Social Sciences Research. Towards higher levels of analysis:  
Progress and promise in research on social and cultural dimensions of health. 2001.  
NIH Publication 21-5020. Ref Type: Report

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5. Otsuka... J Am Acad  
Orthop

6. Rama... tale MG, Do  
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7. Roths... Yu T, Yoon  
CS, W

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complications by attending physicians after performing nighttime procedures. JAMA

2009;302(14):1565-72.

Results

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Discussion

8. Singer B, Ryff C. New Horizons in Health: An Integrative Approach. National Academy Press, Wahington DC 2000.

References

[Google Scholar](#)

9. The Dash Outcome Measure. <http://www.dash.iwh.on.ca/translate.htm>, 2009.

[Google Scholar](#)

10. Vlahovic T, Bumci I. Biomechanical evaluation of the value of osteosynthesis in supracondylar fracture of the humerus using Kirschner pins in children. Eur J Pediatr Surg 2002;12(6):410-5.

[PubMed](#) | [Web of Science ®](#) | [Google Scholar](#)

11. Walmsley PJ, Kelly MB, Robb JE, Annan IH, Porter DE. Delay increases the need for open reduction of type-III supracondylar fractures of the humerus. J Bone Joint Surg (Br) 2006;88(4):528-30.

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