## Clinical Outcomes and Complications of the SIGN Intramedullary Nail: A Systematic Review and Meta-Analysis

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**Purpose:** The Surgical Implant Generation Network (SIGN) supplies intramedullary nails that can be placed without imaging for the treatment of long bone fractures. This study is a systematic review and meta-analysis of the clinical outcomes and pooled complication rate of femoral, tibial, and humeral fracture fixation using SIGN nails.

**Methods:** We electronically searched databases from 2000-2016 for English language studies. There was substantial heterogeneity among studies included. Therefore, we employed subgroup analysis of varying adverse events and removal of potential outlier studies in order to address the heterogeneity across studies. We reported pooled complication rates for each adverse event with 95% confidence interval.

**Results:** There were 14 studies with 47,169 cases across 58 countries. All studies demonstrated >90% full weight-bearing status, range of motion, radiograph union, or clinical union depending on the specific variable measured. The overall complication rate was 5.2% (Fig. 1) with malalignment being the most common complication, followed by delayed/nonunion, infection, and hardware failure.

**Conclusion:** Overall, the use of SIGN nails in fixing femoral and tibial shaft fractures demonstrates good results with a high rate of return to full weight bearing and radiographic union. Complications include malalignment, delayed/nonunion, infection, and hardware failure. Future areas of development may be able to target these challenges.

| Group by<br>Outcome | Study                 | Outcome          | Time point (Months) Statistics for each study |       |                |               |   | Event rate and 95%, CI |
|---------------------|-----------------------|------------------|---|-------|----------------|---------------|---|------------------------|
|                     |                       |                  |   | Event | Lower<br>limit | Upper<br>Emit |   |                        |
| Hardware Failure    | Shah et al            | Hardware Failure | 14.000  | 0.824 | 0.011          | 0.052         | 1 | +                      |
| Hardware Failure    | ficem et al.          | Hardware Failure | 20.099  | 0.025 | 0.004          | 0.157         |   |                        |
| Hardware Failure    | Nacco-ur-Razaq et al. | Hardware Failure | 8.000   | 0.043 | 0.041          | 0.155         |   |                        |
| Hardware Failure    | Panti et al.          | Hardware Failure | 8.005   | 0.621 | 0.003          | 0.134         |   |                        |
| Hardware Failure    | Khan et al.           | Hardware Failure | 6.009   | 0.640 | 0.019          | 0.146         |   | I I <b>→</b> ——I       |
| Hardware Failure    | Stephens et al.       | Hardware Failure | Not Reported                                  | 0.658 | 0.047          | 0.081         |   | i i+- i                |
| Hardware Failure    | Ahmed                 | Hardware Failure | 12.099  | 0.653 | 0.015          | 0.072         |   | I I <b>●</b> I         |
| Hardware Fadure     |                       |                  |   | 0.652 | 0.021          | 0.047         |   | ∔                      |
| Infection           | Shuh et al.           | Infection        | 8.009   | 0.083 | 0.027          | 0.229         |   |                        |
| Infection           | Rem et al.            | Infection        | 20.099  | 0.050 | 0.043          | 0.179         |   |                        |
| Infection           | Nacen-ur-Razag et al. | Infection        | 8.009   | 0.106 | 0.045          | 0.231         |   |                        |
| Infection           | Shearer et al.        | Infection        | 1.008   | 0.050 | 0.047          | 0.053         |   |                        |
| Infection           | Sekimpi et al.        | Infection        | 6.000   | 0.640 | 0.010          | 0.146         |   |                        |
| Infection           | Reeme et al.          | Infection        | 22.000  | 0.108 | 0.041          | 0.255         |   |                        |
| Infection           | Panti et al.          | Infoction        | 8.009   | 0.063 | 0.072          | 0.202         |   |                        |
| Infection           | Young et al.          | Infection        | 3.000   | 0.630 | 0.009          | 0.011         |   |                        |
| Infection           | Zain-Ur-Rehman et al. |                  | Not Reported                                  | 0.038 | 0.012          | 0.110         |   | I []                   |
| Infection           | Stephens et al.       | Infection        | Not Reported                                  | 0.055 | 0.012          | 0.142         |   |                        |
| Infection           | Stephens et al.       | Inform           | Not Reported                                  | 0.654 | 0.003          | 0.042         |   |                        |
| Infection           | Ahmed                 | Infoction        | 12.000  | 0.014 | 0.002          | 0.065         |   |                        |
|                     | Ahmed                 | Indection        | 12,099  |       |                |               |   |                        |
| Infection           |                       |                  |   | 0.048 | 0.024          | 0.0912        |   |                        |
| Malalignment        | Sekimpi et al.        | Malalignment     | 6.009   | 0.680 | 0.079          | 0.195         |   |                        |
| Malalignment        | Panti et al.          | Malalignment     | 8.008   | 0.021 | 0.005          | 0.134         |   |                        |
| Malalignment        | Stephens et al.       | Malalignment     | Not Reported                                  | 0.169 | 0.118          | 0.235         |   |                        |
| Malalignment        | Carsen et al.         | Malalignment     | Not Reported                                  | 0.190 | 0.077          | 0.170         |   | · · •                  |
| Malalignment        | Ahmed                 | Malalignment     | 12.000  | 0.622 | 0.008          | 0.058         |   | •                      |
| Malalignmont        |                       |                  |   | 0.075 | 0.049          | 0.138         |   |                        |
| Nonunion 'delayed   | Shah et al.,          | Nonumion+delayer |   | 0.148 | 0.109          | 0.198         |   | I I -•                 |
| Nonanion-delayed    | Shah et al.           | Nonunion+delayed |   | 0.111 | 0.042          | 0.261         |   | · · · · ·              |
| Nonunion 'delayed   | Rem et al.            | Nommion+delayer  |   | 0.050 | 0.013          | 0.179         |   |                        |
| Nonunion vdelayed   | Nacen-ur-Razaq et al. | Nommion +delayer |   | 0.621 | 0.003          | 0.136         |   |                        |
| Nonunion +delayed   | Sekimpi et al.        | Nonunion+delayed |   | 0.640 | 0.019          | 0.146         |   | · · ·                  |
| Nonunion-delayed    | Topeme et al.         | Nonumion+delayed |   | 0.627 | 0.004          | 0.168         |   |                        |
| Nominion (delayed   | Khan et al.           | Nonumion+delayed |   | 0.180 | 0.096          | 0.311         |   |                        |
| Nonunion (delayed   | Stephens et al.       | Nommion+delayed  |   | 0.019 | 0.006          | 0.057         |   | I I+− I                |
| Nonunion-delayed    | Ahmed                 | Nonunion+delayed | 12.000  | 0.067 | 0.078          | 0.114         |   | I I <b>→</b> I         |
| Nominion Addayed    |                       |                  |   | 0.069 | 0.049          | 0.118         |   |                        |
| Ovenil              |                       |                  |   | 0.647 | 0.056          | 0.060         |   |                        |

