

Distal leg fracture CLIFF Peer Review

1. *Strength of evidence presented in CLIFF in modeling the characteristics and mission impact of this medical condition within the spaceflight environment?*

Score: 3

Grading Scale:

4 - *Confident*

3 - *Somewhat confident*

2 – *Neutral*

1 – *Somewhat unconfident*

0 – *Not confident*

2. How confident are you that these data accurately represent the spaceflight environment?	Tables 1, 2 Composite Incidence and Level of Confidence	Table 3, 4 BC/WC Loss of Crew and probability	Table 4 - Clinical Phase 1, 2 durations Table 5 – CP 2 Loss of Crew	Table 4 – RTDC % Table 6 – RTDC Loss of Crew	Table 4 – Loss of Crew Life % Table 7 – Loss of Crew Life, Loss of Crew	Table 8 – TI
Score	3	2	2	3	4	3

Comments and limitations:

1. **General comments.** For this CLIFF the distal leg was defined as patella, tibia, or fibula. As in other CLIFFs fractures were divided into the categories of traumatic and stress. Notably, ankle fractures are considered separately which can create difficulties differentiating between proximal ankle and distal tibia/fibula fractures. For the purposes of this CLIFF the mesh term "ankle" was excluded in literature searches. There have been no distal leg fractures of any kind in space.

2. **Incidence.** As has been done on other fracture CLIFFs, the risk of traumatic distal leg fractures in microgravity is considered close enough to zero to disregard. The incidence of traumatic fractures during surface EVA's was calculated using terrestrial data and combining multiple studies with large sample sizes. There is good concordance of incidence in these investigations. Stress fractures are a consideration throughout the mission due to the intense exercise regimen that astronauts use to prevent debility of muscle and bone during microgravity operations. A study looking at the risk of stress fractures during athletic training sessions was used to approximate the incidence of stress fractures during astronaut exercise. Thus, separate distributions for EVA operations and for stress fractures were computed. Of interest, studies show that male and female distal leg fracture

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incidences are essentially the same over the age range of astronauts; therefore, a separate distribution by gender was not needed. The BC/WC probability was derived from the only paper that studied all 3 anatomical areas that were considered in this CLIFF (patella, tibia, and fibula). I agree with the calculations of clinical phase durations, RTDC and Loss of crew life probabilities which are supported by terrestrial evidence. The probability density curves that were derived appears to be a reasonable representation of the data presented.

3. Clinical phase 1 data. I am in agreement with the clinical phase 1 duration entered in this CLIFF. This data was compiled by a team of expert clinicians, and I was involved in the discussions leading to the calculation of the clinical phase 1 duration. The CP2 durations listed in Table 4 are the minimum and maximum times found in the literature search based on different fracture types when literature was available (tibial shaft fracture, tibial plateau fracture, patellar fracture, proximal fibular fracture, stress fracture). Thus, the durations values have wide distributions.

4. Task impairment. The analysis was performed and reviewed by a separate team of expert clinicians. I am aware of the methods that were used but did not directly participate in the discussions.

5. Dependence on mission phase or duration of mission. This medical condition is dependent on mission phase, namely EVA surface activities vs microgravity operations.

6. Limitations

- This condition covers multiple different fracture types in the tibia, fibula, and patella. It includes both traumatic and stress fractures. This is a challenge for incidence, duration, RTDC, and Loss of crew life as these numbers vary by fracture type, particularly with regards to stress fractures, which can have a protracted treatment course.
- RTDC values may underestimate the true RTDC because their lower bounds are driven by less consequential fracture types.
- Overall, the confidence in the duration and RTDC is decreased by combining so many fracture types into one condition.
- Little data exists for untreated cases.
- Ankle fracture was left out of the definition of distal leg fractures. It is difficult to define where the distal leg terminates and the ankle begins. Ankle fractures will not be considered in IMPACT 1.0.

Reviewed by:

David C. Hilmer