

## How Safe Are Minimally Invasive Photodynamic Intramedullary Implants?

Christen E Chalmers<sup>1</sup>, Amanda Goldin, Russell Stitzlein

<sup>1</sup>Department of Orthopaedic Surgery

### INTRODUCTION:

Historically, prophylactic surgical intervention for impending or pathologic fractures has included intramedullary nail stabilization or plate fixation with or without curettage and cement augmentation. Recently, photodynamic nail implants have shown promise as a means to provide supplemental fixation through a minimally invasive approach. Indications for this implant continue to expand, particularly in pathologic and osteoporotic bone. However, the minimally invasive nature of this procedure may belie the risk profile of this implant. This retrospective review aimed to evaluate the frequency of intraoperative and postoperative complications associated with this implant.

### METHODS:

We retrospectively reviewed all patients who underwent photodynamic nail placement at a tertiary care hospital between March 2022 and December 2024. Demographics, comorbidities, American Society of Anesthesiologists (ASA) score, surgical indication and technique, and complications were collected. Charleston Comorbidity Index (CCI) was calculated. As the primary outcome and aim of the study was to identify all complications occurring in both the intraoperative and postoperative periods, all patients, regardless of duration of postoperative follow-up, were included in the study. Statistical analyses were performed using Chi-squared ( $\chi^2$ ) tests (or Fisher's exact test when appropriate) and independent samples t-tests (or Mann-Whitney U tests if normality was not demonstrated) to identify clinical or surgical factors associated with complications. P-value < 0.05 indicated significance.

### RESULTS:

Seventy-three patients (33 males, mean age 66.9 years) underwent 77 procedures using the photodynamic implant (Table 1). The mean CCI was 5.97 (range 0-12), with 68.8% of patients with an ASA score of 3. The implant was used to stabilize impending/pathologic fractures (70.1%), non-pathologic fractures with compromised bone quality (16.9%), and nonunion repairs (13.0%). The most common surgical sites were the humerus (64.9%) and pelvis (20.8%). Additional hardware was utilized in 55.8% of cases.

The overall complication rate was 11.7%, including four implant-related complications, three deaths occurring within thirty days, one case of severe intraoperative hemodynamic instability requiring prolonged pressor support, and one surgical site infection. Two of the three mortalities occurred following intraoperative cardiac arrests after inflation of the photodynamic implant. Clinical factors, including age, sex, CCI, ASA score, and oncologic history, were not associated with complications ( $p > 0.05$ ) (Table 2). Surgical factors were also not associated with complications ( $p > 0.05$ ). While neither oncologic history nor surgical indication were associated with complications, all four cases of mortality or intraoperative hemodynamic instability occurred in patients undergoing surgical stabilization of an impending or pathologic fracture for metastatic cancer.

### DISCUSSION AND CONCLUSION:

In this retrospective study, the overall complication rate was low, with almost half of the complications occurring from implant failure or prominence. However, despite the minimally invasive nature of the procedure, photodynamic nail implant use resulted in higher-than-expected intraoperative complications, including death following intraoperative cardiopulmonary arrest. The mechanism for implant filling causes rapid and broad elevation of intramedullary pressure, which can lead to fat embolism and potential cardiopulmonary collapse. Unlike reamed implants, it is not easily possible to create a "vented" system. To date, there have been no previously reported mortalities in the perioperative period during the placement of this photodynamic implant. Proper communication with anesthesia providers and pre-operative counseling regarding these risks is essential, particularly for medically complex patients.

**Table 1: Demographics and Surgical Factors**

	Mean ± SD	Frequency (%) n = 77
Sex (male)		33 (42.8%)
Age at time of surgery (years)	66.9 ± 13.5	
CCI	6.0 ± 3.1	
ASA Score	2.9 ± 0.6	
Oncologic history (yes)		53 (68.8%)
Surgical site		
Humerus		50 (64.9%)
Pelvis		16 (20.8%)
Femur		7 (9.1%)
Tibia		4 (5.2%)
Surgical indication		
Pathologic fracture		43 (55.8%)
Impending fracture		11 (14.3%)
Poor bone quality		13 (16.9%)
Nonunion		10 (13.0%)
Implant augmentation (yes)		43 (55.8%)

Note: CCI = Charleston Comorbidity Index, ASA = Association of Anesthesiologists

**Table 2: Clinical and Surgical Factors Associated with Complications**

	Complication (n = 9)	No complication (n = 68)	p-value
Sex			0.286*
Male	2	31	
Female	7	37	
Age (mean years ± SD)	62.2 ± 6.7	67.5 ± 14.1	0.077†
CCI (mean ± SD)	6.7 ± 2.6	5.9 ± 3.1	0.528‡
ASA Score (mean ± SD)	2.8 ± 0.4	3.0 ± 0.6	0.356‡
Oncologic history (yes)	7	46	0.712*
Surgical site			0.899‡
Humerus	6	44	
Pelvis	2	14	
Femur	1	6	
Tibia	0	2	
Surgical indication			0.480‡
Pathologic fracture	7	36	
Impending fracture	1	10	
Poor bone quality	1	12	
Nonunion	0	10	
Implant augmentation (yes, %)	4	39	0.497*

\* Fisher's exact test

† Independent samples t-test

‡ Mann-Whitney U test

# Chi-squared test