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Dear Dr. irianto:

Thank you for reviewing manuscript # OSJ-21-0111 entitled "Nail-stem construct for recalcitrant nonunion in humeral periprosthetic fracture after total elbow arthroplasty" for Journal of Orthopaedic Surgery.

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Nail-stem construct for recalcitrant nonunion in humeral periprosthetic fracture after total elbow arthroplasty

Journal:	Journal of Orthopaedic Surgery
Manuscript ID	OSJ-21-0111
Manuscript Type:	Original Article
Keywords:	nail-stem construct, total elbow arthroplasty, revision surgery, periprosthetic fracture, recalcitrant nonunion, implant loosening
Abstract:	Purpose: This study aimed to describe the surgical technique used in our innovative nail-stem construct and evaluate patient outcomes for salvaging periprosthetic humeral fractures with recalcitrant nonunion after total elbow arthroplasty (TEA). Methods: Patients diagnosed with implant loosening and periprosthetic fractures subsequent to previous TEA were retrospectively registered between 2018 and 2019. A posterior incision was made on the periprosthetic humeral fracture using the triceps-splitting approach. Without disassembling the prosthetic ulnohumeral joint, the humeral stem was exposed from the humeral intramedullary (IM) canal of the fracture site. A segment of IM nail was measured and inserted proximally into the humeral canal and then pulled back to achieve adequate overlapping on the humeral stem. Cement was then packed into the humeral canal, followed by docking the IM nail into the humeral stem. The nail-stem interface was also cemented to augment fixation, and the harvested strut allograft was wrapped around the fracture site. The wound was closed in layers, and a shoulder sling was applied. The range of motion, degree of elbow stability, and level of pain were evaluated following the procedure. Results: All four patients (average age 78.7 years) achieved full range of motion and secure stability with painless elbow at 12, 16, 24, and 30 months, respectively. Conclusions: Our innovative, low-cost nail-stem construct procedure is a feasible alternative to revise TEA in patients with implant loosening, periprosthetic humeral fractures, and recalcitrant nonunion. Key Words: nail-stem construct, total elbow arthroplasty, revision surgery, periprosthetic fracture, recalcitrant nonunion, implant loosening. Level of Evidence: Level IV

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2	The incidence of total elbow arthroplasty (TEA) has increased in recent years; however,
3	it has a higher percentage of complications and revisions compared to other
4	arthroplasties. ¹ The survival rates of TEA were revealed to be 92%, 81%, 71%, and
5	61%, at 5, 10, 15, and 20 years, respectively. ² Infection, aseptic loosening, and
6	periprosthetic fracture are commonly occurring complications that require revision
7	surgery; whereas, periprosthetic fracture with recalcitrant nonunion in aseptic loosening
8	is the most complex complication following TEA. ^{3,4} This may be related to several
9	factors, including patient age, prosthetic design, and multiple prior surgical
10	procedures. ^{5,6} Besides, ligament deficiency caused by nonanatomic force transmission
11	in semi-constrained implants is the primary reason for substantial bone resorption. ⁷ In a
12	study of 92 TEAs with a mean follow-up of 6.5 years, the rate of mechanical implant
13	failure was 25%, and half of the study population showed aseptic loosening. ⁵
14	Furthermore, the overall complication and revision rates have been reported to be
15	approximately 24% and 13%, respectively. ^{8,9} Fractures around the loose prosthesis
16	associated with massive bone loss are the most technically challenging and common
17	scenarios in revision TEA. ¹⁰ Although revision of the loose prosthesis and reduction of
18	the fracture with allograft reconstruction have been the golden standard of treatment, ¹⁰
19	recalcitrant nonunion may still develop, even with different osteosynthesis methods. To
20	overcome it, we developed an innovative and inexpensive procedure using a nail-stem

21	construct for salvaging this kind of periprosthetic humeral fractures following TEA.
22	Similar approaches in cases of periprosthetic femoral fracture with nonunion after total
23	hip arthroplasty had been reportedly described, which were treated with a nail
24	overlapping the femoral stem tip. ^{11–14} The concept of our nail-stem construct used in the
25	elbow was inspired by the procedures implemented in the hips. To our knowledge,
26	although the basic principle was similar, no report using this technique on the elbows
27	has been published. Herein, we describe the procedures in detail and report the
28	encouraging early results in four patients using the nail-stem construct.
29	
30	Materials and Methods
31	Patients
32	Between 2018 and 2019, we included four patients diagnosed with implant loosening
33	and periprosthetic fractures subsequent to previous TEA (Coonrad-Morrey Total Elbow,
34	Zimmer). The demographics involved patient age, gender, lesion site, the indication of
35	previous TEA, and previous revision surgeries (Table 1). A total of one right and three
36	left elbows underwent the nail-stem reconstructive procedure at our hospital. All four
37	patients were female with an average age of 79.3 years who had previously undergone
38	TEA for rheumatoid arthritis (two cases) and traumatic osteoarthritis (two cases). The
39	patients were reviewed at the Department of Orthopedics of the Buddhist Dalin Tzuchi
40	Hospital, Taiwan. Ethical approval for this study was obtained from the Institutional

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Case 1

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41 Review Board and the Ethics Committee of the Buddhist Dalin Tzuchi Hospital,

A 73-year-old woman underwent left primary TEA 13 years ago due to rheumatoid
arthritis. Periprosthetic humeral fracture around the loosened stem occurred after a fall
five years postoperatively. In the following seven years, a total of five surgeries were
performed at two medical centers, resulting in persistent loosening and recalcitrant
nonunion. The revision surgeries included conventional plate and wire with auto-bone
grafts, exchange with a long stem, and onlay double allo-bone plating (Figure 1). We
used nail-stem construct to treat the recalcitrant nonunion.

51 *Case 2*

A 76-year-old woman with rheumatoid arthritis was referred to our hospital due to
failed osteosynthesis for the periprosthetic humeral fracture. Recalcitrant nonunion
persisted despite three revision surgeries, consisting of locking plate fixation, double
allo-bone plating, and conventional plate and wire fixation with autogenous bone grafts.
We solved this problem after nail-stem construct procedure.

57 *Case 3*

58 An 87-year-old woman presented with acute periprosthetic fracture of the humerus after

a fall. She underwent primary TEA for traumatic osteoarthritis 11 years ago. Aseptic

60 loosening of the humeral stem diagnosed postoperatively. We treated the loosened

61 implant and fracture with nail-stem construct.

Case 4

An 81-year-old woman underwent left primary TEA ten years ago due to traumatic
osteoarthritis. Periprosthetic humeral fracture around the loosened stem occurred after a
fall. The persistent loosening and nonunion occurred despite four times of surgery at
two medical centers. We used the nail-stem construct in this situation.

68 Surgical Technique

The affected arm was placed on an elbow support in the lateral decubitus or prone position. A posterior incision was made with the triceps muscle split at the midline to expose the distal humerus. After identification of the radial nerve, extensive debridement was performed to remove all the previously implanted cement, K-wires, and screws/plate. Without disassembling the prosthetic ulnohumeral hinge, the humeral stem tip was exposed from the intramedullary (IM) canal. The humeral IM canal (Nailing System, Stryker) was then over-reamed at least 2 mm to facilitate smooth nail insertion. The length of the IM nail segment was determined by measuring the depth of the humeral canal. Appropriate nail length should easily dock distally to the tip of humeral stem with 3 to 5 cm of overlap into the stem, and be long enough proximally to reach the humeral head to achieve construct stability (Figure 2). The IM nail was

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80	pushed into the humeral canal and then pulled back distally to establish the construct.
81	This should be practiced several times to achieve the final construct. Then the cement
82	was packed into the humeral canal, and the IM nail was inserted to lead the stem into
83	the IM nail with the interface being cemented to augment fixation. At the final setting of
84	the cemented nail-stem composite, elbow flexion-extension was checked to achieve full
85	range of motion, and the alignment was checked via fluoroscopy. For the periprosthetic
86	bone defect, the harvested allografts were impacted and fixed with cerclage wires. The
87	wound was closed, and a sling protection was implemented for six to eight weeks. A
88	rehabilitation program was initiated on the first day postoperatively.

89

90 **Results**

In our four patients, the average duration from the primary TEA to the final revision
with nail-stem construct was 10.5 years, and the previous number of surgeries averaged
3.5. All the fractures were Mayo classification type II3. For the nail-stem construct
procedure, the surgical time averaged 2 hours 40 minutes, the blood loss averaged 387.5
cc, and the mean hospital stay was 8.5 days (Table 1).

96 Preoperatively, all the patients showed painful disability with deformity and instability.

97 The average preoperative visual analogue score (VAS) was 6.5. Full range of motion

98 with painless and stable elbow was achieved at the 12-, 16-, 24-, and 30-month follow-

99 ups (Figure 3). The postoperative VAS was 1. There were no complications, such as

radial nerve injury, infection, or instability. Triceps insufficiency was observed in Cases 1, 2 and 4, but it was present prior to revision. Radiographically, solid union was achieved at the final follow-up without implant loosening or fracture nonunion in all cases (Figure 1). Discussion Periprosthetic fractures associated with humeral stem loosening remain the most technically demanding due to extensive bone loss, poor bone quality, and soft tissue contracture. Nonunion with persistent loosening of the humeral component continues to occur despite various osteosynthesis techniques, such as plate/screw/wire fixation, locking plate fixation, onlay allograft bone plating, or revision with a longer stem (Table 2). Therefore, we developed an innovative elongation technique to provide a "serviceable elbow" for patients with humeral bone loss following TEA. Currently, this technique performed successfully in our four patients who had failed multiple surgeries. Morrey et al¹⁵ performed allograft prosthetic composite reconstruction for massive bone loss with limited functional restoration. Sanchez-Sotelo et al¹⁶ treated humeral periprosthetic fractures associated with a loose humeral component with implant revision and strut allograft augmentation, resulting in a substantial complication rate. Furthermore, endoprosthetic arthroplasty has been associated with poor outcomes and high complication rates in up to 50% of cases.^{4,17,18} In our study, in relation to Cases 1, 2

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and 4, multiple attempts for osteosynthesis had failed in other hospitals even with the 120 locking plate fixation procedure or revision with a long stem. Martin et al¹⁸ used a 121 122 vascularized fibula graft with double plate fixation for a patient with extensive 123 segmental loss of the humerus. The free fibular graft brings vascularity to the region of 124 humeral nonunion with a background of previous pathological fracture following 125 radiotherapy. In our all cases, union was achieved even in the presence of a suboptimal 126 soft tissue environment because adequate construct stability was achieved. 127 There are multiple benefits of the current nail-stem construct used. First, disconnecting 128 the hinge is not required, and the original humeral and ulnar components can be retained 129 without exchange. It is an inexpensive procedure compared to revision with a long stem 130 or conversion to an endoprosthesis. Second, the IM nail can accomplish an excellent fit with its larger diameter than the very thin humeral stem. Furthermore, the nail can be 131 designed to be as long as necessary to reach the humeral head. Unlike the thin and 132 133 relatively short humeral stem with extramedullary plate fixation in an osteoporotic 134 humerus, this IM construct can provide excellent stability and realign the humeral stem 135 to a functional position. 136 Some technical specifications of this procedure need to be emphasized. First, multiple

trial fit prior to final cementation is essential to achieve smooth and trouble-free

insertion of the whole construct into the humeral canal. Second, suboptimal length of

the nail could lead to a compromise in the range of motion and difficulty in

140	implantation. Third, the overlapping between the nail and the stem should not be less
141	than 3 cm to avoid rotational instability or dislodgment. In a biomechanical model,
142	Melvin et al ²⁰ reported that for a stable stem-nail connection, 2.9 to 3.5 cm of overlap
143	should be achieved. Lastly, full cementation helped maintain the whole construct among
144	the interfaces of the humeral canal, the nail, and the stem. The additional allografts
145	impacted into the periprosthetic bone defect will provide further bone stock. In our
146	experience, there was not any sign of construct loosening despite immediate
147	mobilization from the first postoperative day. All the patients achieved painless and
148	stable elbows early, and were able to return to normal activity.
149	The large and long nail-stem construct can eliminate the development of stress risers
150	commonly seen in the thin and short stems, which were the major problems causing
151	instability and progressive loosening. With a positive result seen in the revision
152	scenarios, we applied this construct method in Case 3 with traumatic osteoarthritis in the
153	primary setting to prevent further periprosthetic fracture with recalcitrant nonunion.
154	However, this needs to be verified in more cases with longer follow-up periods.
155	This study has some limitations. The follow-up time was short, and the case number
156	was small. Besides, it is a technically demanding procedure; therefore, a favorable
157	outcome may not be assured in inexperienced hands. Future studies should include more
158	cases with a longer follow-up period to assess the efficacy of this method.

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8 9 10	159	In summary, we highlighted the nail-stem construct as an innovative, inexpensive, and
11 12	160	durable alternative procedure that can be used successfully in the setting of revision of
13 14	161	TEA without the need for component exchange or hinge disassembly.
15 16 17	162	
18 19	163	Declaration of conflicting interest
20 21	164	The authors declare that there is no conflict of interest.
22 23 24	165	Funding
25 26	166	This study was not funded by any private or government funding agency.
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8 9 10	222	Figure legends
10 11 12	223	Figure 1. Case 1. Preoperative AP (A) and lateral (B) radiographs showing nonunion
13 14	224	after multiple surgery. AP (C) and lateral (D) X-rays 30 months postoperatively
15 16 17	225	showing solid union with stable fixation of stem-nail construct.
17 18 19	226	AP: anteroposterior
20 21	227	Figure 2. Checking the distal fit and adequate overlapping up to 5 cm between the nail
22 23	228	and stem.
24 25 26	229	Figure 3. Case 1. Painless elbow with nearly full range of motion at 5 months
27 28	230	postoperatively.
29 30	231	
31 32 33	232	Tables
34 35	233	Table 1. Patient characteristic following total elbow arthroplasty with periprosthetic
36 37	234	fracture
38 39	235	Table 2. Variable treatment methods of periprosthetic fracture following total elbow
40 41 42	236	arthroplasty
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Figure 1





Figure 2



Figure 3

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 Table 1. Patient characteristic following total elbow arthroplasty with periprosthetic fracture

	Age	Gender	Previous	Reason	Primary	*Mayo	Blood	Operation	Mean	Pre/Post	Union	Follow
			operation	for	*TEA to the	classification	loss	time	hospital	op VAS		time
			times	*TEA	Nail-stem				stay			
			(exclude		construct							
			nail-stem		2							
			construct)		(
Case 1	73	Female	5 times	*RA	12 years	II3	500 cc	2 hours	12 days	6/1	Solid	30
	y/o				1 P			15 minutes			union	months
Case 2	76	Female	4 times	*RA	10 years	II3	400 cc	2 hours	7 days	7/1	Solid	24
	y/o					STD		9 minutes			union	months
Case 3	87	Female	1 time	*TOA	10 years	II3	300 cc	2 hours	7 days	7/1	Solid	16
	y/o						Vi	8 minutes			union	months
Case 4	81	Female	4 times	*TOA	10 years	II3	350 cc	4 hours	6 days	6/1	Solid	12
	y/o							9 minutes			union	months
average	79.3	-	3.5 times		10.5 years	-	387.5	2 hours	8.5 days	6.5/1	-	-
	y/o						сс	40 minutes				

*TEA : Total elbow arthroplasty, *RA : rheumatoid arthritis, *TOA : traumatic osteoarthritis

* Mayo classification: Humeral fractures, H-I : Fracture of the column or the condyles, H-II : Fracture around the stem (II1:Implant well fixed, II2: Implant loose with acceptable bone stock, II3: Implant loose with severe bone loss), H-II3 : Fracture proximal to the stem

Table 2. Variable treatment methods of periprostheti	ic fracture following total elbow arthropla	sty
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	Representative origin	Disadvantage	Advantage
Allograft-	Ilograft- Morrey et al limit functional outcome / unavailable in		recreate a bone stock
prosthetic		allograft shortage hospital	
composites			
Onlay allograft Sanchez-Sotelo J technique demanding procedure /			satisfactory result
bone plating substantial complication rate			
Endoprosthetic	Torbert JT	poor outcome / high complication rate	easy procedure / low technique demanding
arthroplasty			
Vascular graft	Martin et al	difficulty with vessel end to end due to	vascularity brings bone regeneration ability
+ plating		fibrosis and scarring	
Nail-stem	JT chien	technique demanding procedure / need	Inexpensive/ innovative / durable alternative
construct		longer follow time	procedure