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<u>Title</u>: Percutaneous Reinforced Cementoplasty Using Spindles as a Palliative Option for Malignant Fractures of the Humerus

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<u>Key words:</u> Percutaneous cementoplasty, Augmented osteoplasty, Pathological fracture, Humerus, Polymethyl Methacrylate

Abbreviations and acronyms:

CT: Computed tomography IV: Intravenous PMMA: Polymethyl methacrylate RC: Reinforced cementoplasty VAS: Visual analogue scale The humerus is the second most frequent long bone site of metastatic disease [1]. Percutaneous cementoplasty is a minimally invasive alternative for patients with malignant humeral fracture unsuitable for surgery, but polymethyl methacrylate (PMMA) resists poorly to torsional forces and shear stress and is considered less effective for treating long bone tumors, with an increased risk of secondary fractures [2,3]. Various strategies have been proposed to increase the resistance of PMMA in humeral fractures, but these studies are limited to case-reports [4–7]. The present study describes a procedure of percutaneous reinforced cementoplasty (RC) for humeral pathological fractures using intralesional spindles based on a technique described in the cervico-trochanteric region [8].

<u>Procedure</u>

This is a monocentric observational retrospective study. All the spindle-reinforced cementoplasty procedures of the humerus performed at our Institution between January 1st, 2017 and January 1st, 2020 were reviewed. All the patients were discussed during a weekly multidisciplinary meeting dedicated to cancerous bone disease involving interventional radiologists, orthopedic surgeons, medical and radiation oncologists to validate the indication of RC. To be considered eligible for RC, patients had to meet the following criteria: (1) pathological fracture of the humerus causing pain and functional impairment (2) inability to undergo surgical treatment because of poor general condition, need for a systemic chemotherapy, or refused surgery.

All procedures were performed under general anesthesia, in supine position with both arms placed along the body, in a hybrid angiosuite that combines a flat panel C-arm and a dedicated CT scan (16row) (Miyabi Emotion 16, Siemens, Erlangen, Germany), by interventional radiologists with expertise in musculoskeletal interventional radiology ranging from 2 years to 30 years. At the beginning of the procedure, 1 g intravenous (IV) cefazolin (or other broad-spectrum antibiotics) was administered to minimize any risk of infection. An 8-gauge 150-mm bone needle (Thiebaud, Margencel, France) was inserted in a cranio-caudal fashion into the humeral head, laterally to the acromion, in the long axis of the humerus and advanced distally to the fracture site in the medullary cavity, under fluoroscopic guidance. A biopsy at the fracture site was systematically performed to confirm the malignant nature of the disease. Additional 11-gauge bone needles were inserted, under fluoroscopic guidance, transversally to the shaft of the humerus, into the lytic lesion, at the discretion of the operator for additional PMMA bone cement injection. 2.5-mm diameter spindles with length of 5-cm, 7-cm or 8cm cm (material: stainless steel in accordance with the international standard AISI 316 L [Thiebaud]) were inserted through the 8-gauge needle and pushed by means of the mandrel to be placed in the medullary cavity of the humerus, across the fracture site (Figure 1). The choice in size of the spindles was left at the discretion of the operator depending on the size of the lesion. For patients with other lytic lesions adjacent to the fracture site, additional spindles were inserted to form a steel frame in the medullary cavity across all the lesions. After control X-ray, PMMA bone cement (Biomet UK Ltd, Bridgend, UK) was injected into the needles to ensure a satisfactory filling (defined as superior to 50%) of the lesion and the fracture site. A post-operative CT-scan covering the treated humerus was systematically acquired to assess cement distribution, look for potential leakages, and to serve as a reference for the follow-up.

For retrospective analysis, medical records were screened until May 15th, 2021. The following data was sought: secondary fractures, pre- and post-procedure pain estimation at 6 weeks using a visual analogue scale (VAS), technical success of the procedure, number of needles used during the procedure, number of spindles inserted at the fracture site, volume of PMMA injected, additional radiation therapy, and procedure-related complications. The occurrence of secondary fractures was defined as any one of the following events during the follow-up, attested by CT-imaging or plain radiographs: (1) any new fracture of the treated humerus (2) fracture of the cement plug (3) secondary displacement at the fracture site. Procedure-related complications were divided into major (death, permanent sequela, or symptomatic leak) and minor (transient pain, asymptomatic leak, or puncture site hematoma) complications and were graded according to the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) classification [9].

Baseline, per and post-procedural data are summarized in Table 1.

Discussion

Different strategies have been proposed to increase the resistance of PMMA cement to torsional forces and shear stress in long bones, but only a few case-reports emphasize the humerus. The use of cement-filled catheter has been reported [4,5]. Anselmetti et al. [7] described a percutaneous osteoplasty technique using metallic tunnelers designed for central venous catheter placement. Kelekis et al. [6] performed augmented cementoplasty of the humerus using a combination of microneedles and bone cement. Percutaneous screw fixation has been described in the shoulder girdle for fractures involving the scapula [10], but no case-report was found in the literature for humeral pathological fractures. We used the same approach previously described by Premat et al. [8] for the treatment of malignant lesions of the cervicotrochanteric region, with the use of dedicated long bone spindles in addition to PMMA cement. The main advantage of this technique of RC is its simplicity: the 8-gauge bone needle can be placed accurately using only fluoroscopic guidance, one bone needle was needed in most procedures (4/6), and intralesional spindling and cement injection can be performed through the same needle. All complications observed in this series were considered minor complications, as they were asymptomatic. Cement leakages around the fracture site represented most of the complications (3/6). In one patient, two spindles migrated through the fracture site immediately after their insertion with their tip protruding in soft tissues. This is a potential limitation of this technique as it is almost impossible to reposition a misplaced spindle. This patient didn't report any residual pain during follow-up. No secondary fracture was observed, which suggests the efficacy of this procedure on bone consolidation. However, advanced imaging techniques and post-processing tools will help in the future to better evaluate the absence of secondary fracture, especially cement plug fragmentation [11,12].

To the best of our knowledge, this is the largest series of RC for malignant fractures of the humerus. With experimental studies questioning the efficacy of augmented osteoplasty in long bones [13], larger comparative trials would be needed to assess the efficacy of these procedures.

<u>Disclosure</u>

All the authors declare no conflict of interest regarding this study.

Figure 1: Fifty-one-year-old woman with multiple myeloma. **a.** multiple osteolytic formations of the right humerus involving the epiphysis, metaphysis et diaphysis (black stars) with a displaced diaphyseal fracture (black arrow). An 8-gauge bone needle is inserted cranially in the long axis of the humerus, and a spindle is placed across the fracture site. **b.** post-procedure imaging showing spindles placed across the fracture site and a satisfactory cement filling of the osteolytic lesions. **c.** CT-scan performed 35 months after the RC showing consolidation of the diaphyseal fracture around the cement plug (white arrows).



Patient	1	2	3	4	5	6
Age (years)	46	70	61	51	70	58
Sex	М	F	М	F	М	М
Primary tumor	Colon cancer	Multiple	Multiple	Multiple	Multiple	Multiple
		myeloma	myeloma	myeloma	myeloma	myeloma
Side	Left	Left	Right	Right	Left	Left
Fracture	Metaphysis	Metaphysis	Metaphysis	Diaphysis	Metaphysis	Metaphysis
location						
Displacement	No	Yes	No	Yes	Yes	Yes
Number of	1	1	1	1	3	3
bone needles						
inserted						
Number of	NA	NA	7	NA	30	12
spindles						
inserted						
Volume of	NA	NA	25	NA	20	21
PMMA (ml)						
Vertebroplasty	No	No	Yes (T11,	No	Yes (T2, T5, T9)	No
in the same			T12, L4)			
intervention						
Total	112	80	130	58	122	140
procedure						
time (minutes)						
Total	17	11.8	39	15	NA	NA
fluoroscopy						
time (minutes)						
Procedure-	Minor:	Minor:	No	No	Minor: Two	Minor:
related	Leakages	Leakages			spindles	Leakages
complications	(subacromial-	(subacromial-			protruding	(soft
	subdeltoid	subdeitoid			from the	tissue)
	bursa)	bulsaj			fracture site	
					(asymptomatic)	
Radiation	Yes	No	Yes	No	Yes	No
therapy						1
Duration of	35.8	4.5 (death)	1./	46.5	14 (death)	15.6
follow-up						
(months)	10	10	10			10
Baseline VAS	10	10	10	9	8	10
VAS at 6	U	4	2	1	U	2
weeks						
Secondary	NO	NO	No	No	NO	NO
fracture at the						
last follow-up						

NA: Not available, VAS: Visual analogue scale

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