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Original article

DIPHOS® nail for proximal humeral fractures: our experience with more than 190 procedures and surgical tips

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Abstract. *Aim:* evaluate the outcome of proximal humeral nailing over 5 years follow-up, focusing on possible complications. Secondary endpoint is the description and the analysis of some technical notes to simplify the surgical procedure. *Materials and Methods:* the cohort is composed by 194 fractures fixed with short nail. Neer Classification was used to assess the type of fracture; Deltoid Tuberosity Index (DTI) was applied to verify local bone quality. Follow-up with X-rays and orthopaedic evaluation was conducted on every operated subject. *Results:* mean follow up of the study was 25.4 months. We registered an average CMS score of 84.66 points for 2-parts fractures, 79.05 points for 3-part fractures and 68.62 points for 4-parts fractures. We obtained radiographic healing in 95.9% of patients (186/194) after 2.7 months on average. We recorded "very good" / "good" results in 90.3% of 2-parts fractures, 88.5% of 3-parts fractures and 46.2% of 4-part fractures. Overall complication rate was 10.3% (20/194 nails). Second surgery was performed in 8.2% (16/194) of cases. *Conclusion:* intramedullary nailing is an effective treatment for 2 and 3-part fractures with relatively low incidence of complications, small surgical access and short surgical time. Future researches are necessary to analyze the results related to nailing in 4-fragment fractures, still uncertain and influenced by multiple factors. The presence of the intramedullary nail reduces the lever arm of the screws making the osteosynthesis more reliable. Modern nails guarantee angular stability for proximal cancellous screws and allow 1 or 2 screws at calcar level to get a valid medial support. (www.actabiomedica.it)

Key words: Humeral nail, Nailing, Proximal Humerus fractures, Entry Point, Nailing tips, Deltoid Tuberosity Index

Introduction

Proximal humerus fractures are the most common fracture of the humerus, as well as the most common fracture at the shoulder girdle (3). They represent 4–7% of all fractures in adult patients (1–2) and, if we consider osteoporotic patients, they are the third most frequent fracture registered (6).

Because of multiple reasons, often this kind of fracture is treated conservatively, particularly in elderly patients, where this solution can be suitable in 80% of cases (4–5).

The most used classification for these kind of fractures is the Neer classification (7). Its great advantage is the creation of six homogenous groups of fractures, allowing surgeons to choose the best therapeutic path to follow. It takes into account the four principal segments of proximal humerus (as head, great tuberosity, lesser tuberosity and shaft), giving major importance to the displacement of fragments in comparison with the level of fracture or the traumatic mechanism.

The surgical option of nailing is usually reserved to simple fractures as 2-fragments type according to this classification. Difficulties during the reduction

process, complications related to poor bone quality, loss of fragment reduction or humeral head varus deviation, are the principle reasons which lead surgeons to avoid this surgical technique and to prefer other therapeutic possibilities.

Aim of our study is to evaluate the outcome of proximal humeral nailing over 5 years follow-up, specifically focusing on possible complications. Furthermore, we describe and analyze some technical notes to simplify the surgical procedure.

Materials and Methods

We analyzed the database coming from our Orthopaedic Department which reports from January 2014 to December 2018 a total of 1021 proximal humeral fractures. Of these, 239 have been surgically treated, equal to the 23.3%. Dividing our data by type of surgical treatment, we recorded 194 nails, 28 plates, 9 prosthesis and 8 K-wires or external fixation.

We carried out a retrospective study on patients treated with short humeral proximal nail. Exclusion criteria for nailing were: three or four-part fracture dislocations, head-splitting fractures, pathological fractures, open fractures, severe ipsilateral injuries to the shoulder girdle, accompanying neurovascular injuries, patient age under 18 years old and involvement of the diaphysis requiring long nail. We considered suitable for nailing also: fracture with Head Shaft Angle < 105° (varus displacement), Head Shaft Angle> 180° (valgus displacement), displacement of the tuberosities more than 5 mm, less than 50% contact between the shaft and the head fragments.

This specific cohort is composed of 193 patients: 77 males (39.9%) and 116 females (60.1%), one patient underwent a bilateral procedure (Table 1). Mean age is 66.4 ± 5.6 years (min. 52 – max.81). In 11 patients (5.7%) an ipsilateral fracture was diagnosed together with the proximal humerus one: 7 patients (3.6%) reported a wrist fracture (5 isolated fracture of the radius, 1 isolated fracture of the olecranon, 1 forearm fracture); of them, 3 were treated with conservatively (plaster cast) and 4 with surgical procedure; 3 patients (1.6%) reported a proximal femur fracture, always treated with surgery (2 pertrochanteric fractures treated with intramedullary nail, 1 transcervical fracture treated with hemiarthroplasty). On the other hand, 3 patients (1.6%) reported a contralateral proximal humerus fracture as well, but in all cases the surgical indication was given for only one arm and the other was handled conservatively, immobilizing it in a sling.

In all cases we implanted Diphos® humeral proximal nail (LimaCorporate, San Daniele Friuli (UD), Italy). This nail shows specific features such as polymeric material (cfr peek) of the proximal part which creates an effective anti "pull-out" system for proximal screws, avoiding galvanic corrosion phenomena between screws and nail and permitting an exceptionally easy removal. Diphos nail allows multiple configurations of proximal screws positioning, a screw completely dedicated to the stabilization of the greater tuberosity and a couple of screws to support medial calcar.

In all cases each patient was preoperatively evaluated in order to plan the surgery: we used the Neer Classification (7) to assess the type of fracture and we calculated the Deltoid Tuberosity Index (DTI) in

Table 1. Distribution by Fracture Complexity

Neer Class	N=	%	Sex	DTI	DTI/Sex	Surgical Time min (min - max)
2 parts	103	53,1%	40 ♂ 63 ♀	1.380	1.42 1.36	29.8 (20–38)
3 parts	78	40,2%	33 ♂ 44 ♀	1.375	1.42 1.35	36.9 (27–68)
4 parts	13	6,7%	4 ♂ 9 ♀	1.348	1.41 1.35	46.5 (36–71)
	194	100%	193			

order to verify local bone quality (8). We measured immediately above the upper end of the deltoid tuberosity where the outer cortical borders become parallel and DTI (Figure 1) equals the ratio between the outer cortical and inner endosteal diameter.

We recorded time of surgical procedures (Table 2). After dismission every patient underwent a follow-up based on X-rays and orthopaedic evaluation through the Constant Murley Score (CMS). Functional outcomes were rated very good with CMS>86, good 71–85, fair 56–70, poor<55. These assessments were performed after one, two, three, six and twelve months and every year on.

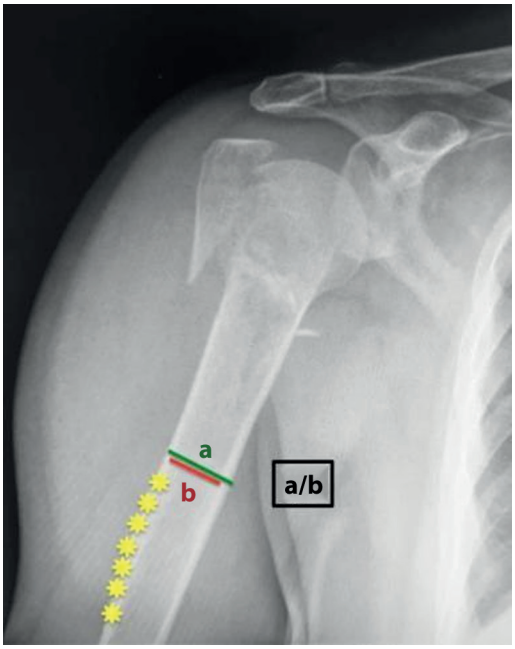

Figure 1. Deltoid Tuberosity Index.

Ethical approval

All procedures performed in studies involving-human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Ethical approval was not obtained directly for this article, but was merged with a parallel study (568/2020/OSS*/AUSLPC, prot. n. 2020/0065297, 29/05/2020).

Surgical Procedure and Tips

The correct position of the patient and the room setting are primary factors to reduce intra-operative problems and safely perform the procedure. All patients treated with short nail were placed in beach chair position which allows clear access to the shoulder and, thanks to the effect of gravity, promotes a natural reduction of the fracture (Figure 2). Positioning the image intensifier posterior to shoulder, with the arch

Figure 2. Patient placement.

Table 2. Clinical Outcomes

Fracture Pattern	Cases	CMS	Very good/ Good (cases - %)	Fair (cases - %)	Poor (cases - %)
2-parts	103	84.66	93 – 90.29	9 – 8.74	1 – 0.97
3-parts	78	79.05	69 – 88.46	7 – 8.97	2 – 2.56
4-parts	13	68.72	6 – 46.15	4 – 30.77	3 – 23.08

tilted perpendicularly to the proximal humerus, allows surgeon to work laterally to the patient and to easily perform serial checks.

In all procedures we follow the same surgical steps: first fracture reduction, reconstructing meta-epiphyseal portion by lifting humerus head, reducing the greater tuberosity and temporarily stabilizing with K-wires; second, choosing the adequate entry point; then, stabilization with proximal screws and finally synthesis with distal screw(s).

Usually the main concern in case of pluriframmentary fracture is to achieve a good reduction, particularly of the head articular surface. This part of the humerus is often impacted in valgus, making it almost horizontal, and it can be raised by introducing a small Kelly forceps through small incisions and lifting the humeral head (Figure 3a.). In more complex cases, a beater with disto-proximal and latero-medial direction may help. These two techniques can be associated. Our aim is to avoid varus malalignment (head-shaft angle<120°) which significantly reduce the risk of fixation failure (12–13).

In order to obtain a good outcome and make the procedure reproducible is fundamental to get the perfect entry point. The use of K-wires temporarily permits the stabilization of the head (Figure 3b.) and by instance, using one or more of them as a "joystick", allow the rotation of the humeral head as a single fragment. An antero-posterior direction with an inclination of about 30° is the best way to manage the humeral head. To understand the adequate orientation of fragments a useful tip is to extra-rotate the proximal humerus until the spherical shape of the head and the greater tuberosity can be seen forming the profile of a Beetle car (Figure 3c.). Once this correct image has been obtained (Figure 3d.), checking the third plane, it is possible to have a "three-dimensional" view.

As far as choosing the surgical approach, there are different possibilities, both in percutaneous and mini-open accesses (14). This decision is not only operator dependent, but needs to consider also patient's characteristics, such as age, functional demands, and the eventual inveterate lesion of the rotator cuff. We usually adopt the percutaneous technique, trying to keep the entry point medially, closer to supraspinatus muscular portion (15).

After nail introduction, we fix tuberosity fragments with screws as perpendicular as possible to the fracture line adding one or two screws to support calcar head area (all cancellous angular stability screws). Finally we conclude distal stabilization with cortical screws (Figure 3e).

In the postoperative phase, the operated arm has to be kept in a sling for 3 weeks with no load allowed. After this phase, patients start a passive physiotherapy with progressive range of movement (ROM) in accordance with pain; flexion-extension, abduction-adduction and elevation of the arm are allowed. Since the end of the 5th week after surgery, an active physiotherapy is permitted.

Results

From the analysed data we noticed a correlation between gender and bone quality measured with DTI. Males registered higher values than females, reflecting a better bone quality. Instead, we did not see a clear correlation between the complexity of fracture pattern and the DTI. Mean follow up of the study was 25.4 months (min 9 – max 58 months). In case of regular postoperative course, we handled clinical check-ups after 1-2-3-6-12 months; instead, X-rays checks with anteroposterior and later views were obtained at the outpatient clinic after 1-3-6-12 months from surgery. Then, every patient underwent annual clinical evaluation along with objective assessment with the CMS score; only in case of clinical issues patients went through radiographic control as well.

During outpatient visits, the use of the Constant Murley Score (CMS) allowed an objective clinical evaluation of every fractured patient. We carried out the CMS for every patient, at 6 months follow-up. Considering the fracture pattern, we registered an average CMS score of 84.66 points for 2-parts fractures, 79.05 points for 3-part fractures and 68.62 points for 4-parts fractures (Table 3).

We obtained radiographic healing in 95.88% of patients (186/194) after an average time of 2.7 months (min 2 – max 5 months). As shown in Table 3, we recorded a "very good" / "good" results percentage in 90.3% of 2-parts fractures and a percentage in 88.5%

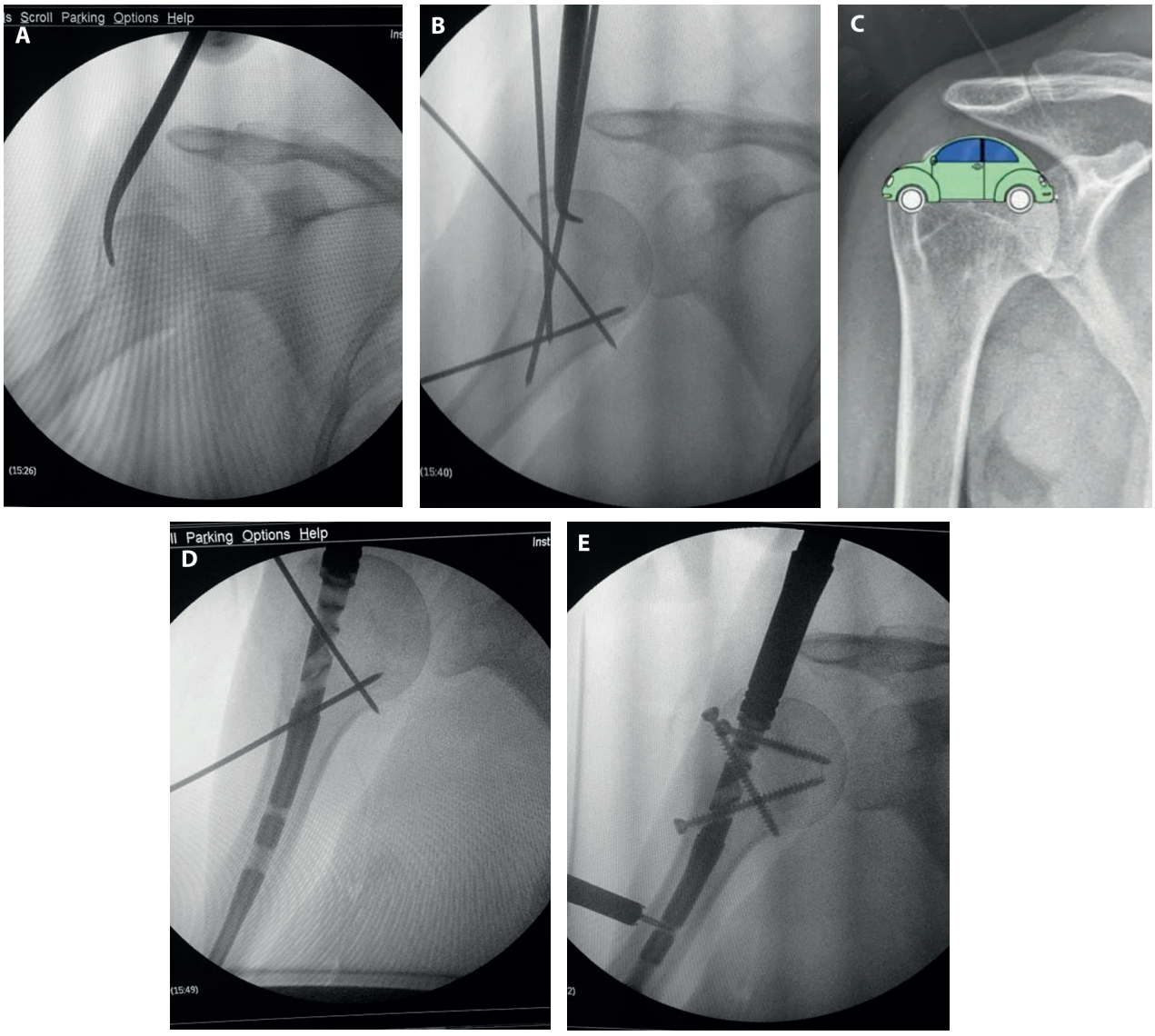

Figure 3a. Lift humeral articular surface. **b.** Temporary stabilization. **c.** Humeral head extrarotation. **d.** Nail introduction. **e.** Final fixation.

on 3-parts fractures. On the other hand, in 4-part fractures this outcome was registered on the 46.2%, but it was "poor" only on the 23.1%. Overall complication rate was 10.3% (20/194 nails). Specifically, we registered a complication rate of 7.8% in 2-parts fractures (8/103), 10.6% in 3-parts fractures (8/78) and of 30.8% in 4-parts fractures (4/13).

Four of these complicated cases could not be surgically managed, since two patients refused the proposed treatment while the other two presented an high anesthesiological-surgical risk. Second surgery was performed in 8.2% (16/194) of cases (Table 4): 4 screw removals (25.0%), 4 reverse prosthesis (25.0%), 3 arthroscopic lysis and mobilization (18.7%), 2 nail removal and subacromial lysis (12.5%), 2 revision osteosynthesis (12.5%) and 1 debridement + antibiotic therapy (6.3%). In the total 16 revisions, we obtained a complete resolution in 68.7% of cases (11/16), a clinical improvement in 25% (4/16) and no significant changes in 6.3% of cases (1/16).

We removed 11 nails (5.7%): 4 for reverse prosthesis, 2 patients<50 yo during arthrolysis after

Table 3. Complications

Complication	N=	%	Neer Classification	Solution
Early superficial Infection	1	5%	(1) 2 parts	1 Debridment and antibiotic
Loss of tuberosity reduction	4	20%	(3) 3 parts (1) 4 parts	3 No treatment 1 Reverse prosthesis
Extrarticular screw overhang	3	15%	(2) 2 part (1) 3 parts	3 Screw removal
Intrarticular screw overhang	1	5%	(1) 2 parts	1 Screw removal and replacement
Aseptic humeral head necrosis	1	5%	(1) 4 parts	1 Reverse prosthesis
Nonunion	2	10%	(2) 2 parts	2 Revision osteosynthesis
Stiffness	6	30%	(2) 2 (1) 3 (1) 4	1 No treatment 3 Arthroscopic lysis and mobilization 2 Nail removal and subacromial lysis
Post-traumatic Arthritis	2	10%	(1) 3 parts (1) 4 parts	2 Reverse prosthesis

fracture healing, 2 during revision surgery for non-union (1 plate and autologous bone augmentation, 1 reaming and new nail with more static fixation, both healed after revision), 3 patients<40 years after fracture healing.

Discussion

Our findings are similar to the date reported by Toon Dong Hao et al. (16), who reported that intramedullary nailing can be an effective option for displaced Neer's 2 and 3-part proximal humeral fractures, with good early functional and radiological outcomes as well as low rates of complications. On the other hand, the treatment of 4-part fractures with nail seems to have an inferior outcome, suggesting that further studies with larger cohorts of patients could be useful to clear the role of intramedullary nailing in this kind of fractures.

Patient age, osteoporosis, varus displacement, medial comminution, articular surface involvement, reduction adequacy, and insufficient medial support must be taken into consideration for the surgical technique choice and show significant correlations with reduction loss (17).

As far as bone quality, we preferred to use the DTI rather than the Tingart measurement (TM) (9). In fact, the TM shows better correlation with DXA measurements of different anatomical sites (10–11), but required landmarks are often involved in fracture. An other disadvantage of TM is that millimetre value must be adjusted for radiographic magnification and references are not always reliable on radiograms. Spross et al. (8) confirm that deltoid tuberosity index is correlated strongly with local bone mineral density (BMD) of humeral head and it is a reliable, simple, and applicable tool to assess local bone quality in the proximal humerus; values consistently lower than 1.4 indicate low local BMD of the proximal humerus.

As shown in our series, many patients with proximal humerus fracture had poor bone quality with DTI values>1.4, especially women over 75 years. We didn't notice a clear correlation between bone quality (deltoid tuberosity index) and fracture pattern, but we can't consider our data reliable about it, since we only analyzed fractures treated by nailing and not all humerus fractures.

In literature, many authors (18,19) suggest augmentations to support surgical reconstruction (with cages, bone blocks heterologous or synthetic, PMMA, etc..) for poor bone quality patients. We believe this problem could be more relevant using plates than nails, in fact we didn't notice any case of head varization after the osteosynthesis. This is probably because nail proximal apex becomes a valid mechanical support of proximal humerus.

Humeral head, like femoral one, sustain varus stresses. As already demonstrated for femur nailing,

the presence of the intramedullary nail reduces the lever arm of the screws making the osteosynthesis more reliable (20). Gadea et al. (21) compared the clinical results of nails and plates in 4-fragment fractures, finding out that plates have better results in case of preserved medial hinge, while there isn't any difference in case of calcar comminution and interruption of the medial hinge; in this second case, nails would have a greater risk of varus deformity. However, in this work they used different types of nails. We believe that the surgical technique is fundamental for the intraoperative fracture reduction, but the specific features of nails are critical to guarantee an effective medial support and to stabilize humeral tuberosities with an angular stability system for proximal screws.

Modern types of nails, like Diphos®, guarantee angular stability for proximal cancellous screws and allow 1 or 2 screws at calcar level to get a valid medial support. Recent works such as the one by Plath et al. (22) confirm our data and our hypothesis: on a cohort with average age higher than our, they carried out a comparative study between plates and nails with calcar support; patients treated with nail reported both a better functional results (evaluated with DASH score) and a lower incidence of secondary loss of reduction and screw cut-out. Moreover, the coupling of nail and screws made of two different materials (titanium and peek) avoids the risk of cold fusion, which is essential for an eventual removal, without affecting the mechanical strength of the nail. We didn't observe any nail or screw breaking in our study.

Concerning the treatment of 4-fragment fractures, nailing isn't an option considered by many algorithms in literature (23) and our findings seem to confirm that this device is not suitable for complex fractures. Other authors such as Sosef et al. (24) confirm a higher incidence of failure compared to simpler fracture patterns and poorer results. However, Pastor et al. (25) reported an average CMS of 57 in patients with 4-part fracture treated with reverse prostheses. We registered 14 cases of 4-parts fractures in our cohort: 4 of them reported complications, while 9 of them achieved good results. These data lead us to believe that, today, surgeons don't have any device allowing them to manage this kind of fractures with the certainty of successful outcomes.

Nonetheless, the findings of this study have to be seen in light of some limitations. The first and most important one is that this surgical procedure is not standardizable, although we have exposed some tricks that can help in the success of the procedure, and results are deeply influenced by surgeon's experience. More than 90% of patients belonging to this cohort were operated by a single surgeon, with consistent experience in this specific trauma surgical field. Furthermore, the group of 4-fragments fractures is poor. It would be interesting to have more available data about the post-surgical outcomes of this type of fracture, since it is the one with the most complications and the worst outcome. Finally, we don't report a direct comparison with an alternative osteosynthesis device, because we usually prefer to treat these fractures with intramedullary nail, so our data about other surgical procedures are very poor.

Conclusion

Intramedullary nailing is a safe and effective treatment for proximal humerus fractures especially for 2 and 3-part fractures ensuring good clinical results and relatively low incidence of complications. The already known advantages of nailing are the chance to have small surgical accesses combined with shorter surgical times. Moreover, recent introductions like design innovations and new technical features permits to face and solve many issues such as poor bone quality, medial wall interruption, calcar comminution, tendency of loss reduction with humeral head varus deflection that could affect clinical outcomes. Future researches are necessary to analyze the results related to the use of nail in 4-fragment fractures, which is still uncertain and influenced by multiple factors; reliable data are difficult to collect since surgeons choose this device only in selected cases, using different surgical techniques, different implants and only if at ease with this therapeutic choice.

Conflict of Interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

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