

POSITION

By Prof. Dr. Dian Enchev, Ph.D

Head of First Orthopaedic Traumatology Clinic

At UMHATEM N.I. Pirogov

With reference to: Dissertation paper submitted by Dr. Stoyan Zhelyazkov Hristov on the thesis:

“Operative treatment of proximal humeral fractures by locking plate with and without augmentation-comparative analysis” for awarding an educational and scientific Doctorate degree /Ph. D./ in higher education area 7. “Healthcare and Sports” in professional direction 7.1 “Medicine” and scientific specialty “Orthopedics and Traumatology”

Presented position is in compliance with the requirements of Academic Development Act in Republic in Bulgaria, Rules for implementation of this Act, and article 31/ 1 of Rules for development of academic staff at UMHATEM N. I. Pirogov. In accordance with decision by Scientific Council Nr. ND-01-1/ 14.02.2022 and order Nr. RD -26-521 for admitting the individual doctorate candidate Dr. Stoyan Hristov to a dissertation defense in specialty Orthopedics and Traumatology. Following a remote session of Primary scientific unit and order Nr. RD-26-523/14.02.2022 by the Director of UMHATEM N. I. Pirogov I was appointed as a member of the Scientific Jury with assignment to provide scientific position on the dissertation paper.

Proximal humeral fractures (PHFx) involve mainly elderly population same as fractures of femoral trochanter area and distal radius fractures. Major treatment goal is to preserve biological joint by achieving anatomic reposition and stable fixation. Stable fixation itself is hardly achievable considering progressed osteoporosis, comminution and anatomic specifics of proximal humerus. Fixation by locking plate (LP) is undoubtedly a progress in this direction since they ensure more stable osteosynthesis. In last 20-30 years there is a number of publications providing good outcome records when treatment of PHFx is conducted by these implants. Based on above indication for operative treatment have increased. In previous years for patients over 75 a functional orthopedic treatment was considered as the proper method for a good functional outcome, while nowadays most authors differ from this opinion and prefer operative treatment. However, LP broadening indications and widespread use in last years led up to a significant growth of complications up to 49% - AVN, de bricolage, screw penetration, improper healing (mal-union), non-healing, subacromial impingement, adhesive capsulitis etc. Of course there are fractures and fracture-dislocation, where osteosynthesis is not possible and in such cases the reasonable option is primary prosthesis of shoulder joint – with anatomic or reversed artificial shoulder joint. This seems as a reasonable decision in cases of patients over 75-80 years.

However, results are pretty much disputable. Functional recovery is not universally good. Prosthesis longevity is problematic as well and the specific complications related to artificial shoulder joint, occurring with the time progress. Above stated is the reason for more and more publications in last 15 years dealing with additional strengthening aka "augmentation" of the osteosynthesis in patient cases with obvious osteoporosis and comminution aiming more rigid fixation, bone healing and finally preservation of biologic shoulder joint. First publications on this issue are related to infero-medial screw position, providing additional support in order to avoid secondary varus. Later on applying of bone form pelvic iliac crest and frozen tibia was implemented. Filling the bone void in the metaphysis and the augmentation of the osteosynthesis can be performed with bone cement/PMA/ as well. The method's advantage lies in its capacity to fill evenly the void, to envelop the screws and distribute the load forces, to reduce cutting forces in subchondral area and thus to consolidate the osteosynthesis. The method is easily available. However, some questions come into consideration such as whether there will be negative impact on the cartilage during cement hardening and thus resulting rising temperature.

The dissertation thesis "Operative treatment of proximal humeral fractures by LP, with and without augmentation-comparative analysis", presented by Dr. Stoyan Hristov, deals with a currently hot issue. Dr. Hristov develops and answers the question about potentials of osteosynthesis augmentation by LP with PMA in PFX in patients with osteoporosis and complex pathological morphology.

The thesis has a classical structure. In the introduction and the beginning the author states the major problems. Surgical anatomy, approaches, various treatment methods have been presented clearly and in details, related to present study. Surgical technique has been described in full.

The dissertation goal is formulated brief and clearly- to analyze potentials of PMA augmentation in operative treatment of PFX by locking plate.

There are four tasks stated and all of them are logically related to the assigned goal- to conduct a review and analysis of treatment methods of PFX, to apply all three methods of fixation by LP, with and without augmentation in sufficient cases of patients with comparable specifics- age, fracture morphology and bone quality, to perform analytical analysis of achieved results, complications and necessary secondary interventions in all three groups, treated by LP with and without augmentation in order to develop an action algorithm in cases of patients with PFX, which can be implemented in the praxis.

Author's research includes 112 patients with 114 PFX. Average age is 67, 103 (90.4%) patients are women, 11 (9.6%) - men, which is 9: 1 ratio. Monitored group consists of 68 (59.65%) patients over 65 and within women cases 82 (79.6%) are over 60 years.

All fractures in the target group are closed, without neurologic damages, and classified according Neer's classification as 3- fragment (88.6%), two of them with fracture-dislocation (1.8%) and as 4- fragment (11.4%). In 25 fracture cases (22.0%) the treatment method is augmentation with bone autograft (BA) from pelvic iliac crest. 25 fractures (22.0%) have a PMA augmentation. In 64 fracture cases (56%) the performed osteosynthesis with LP is without any augmentation. The reposition assessment criteria used are the well known **Schuetzke et al.** criteria. X- ray and functional outcome have been classified according Constant- Murley score and DASH score (Bulgaria).

10.04.2022

Sincerely:

Prof. Dr. Dian Enchev, Ph. D.

Considering the above stated I believe the dissertation paper of Dr. Stoyan Hristov in its qualities entirely fulfills the criteria for obtaining the scientific and educational degree Ph. D.

In my opinion the dissertation paper of Dr. Stoyan Hristov is a research with scientific and practical value. The topic addresses a current problem, is well developed and represented by the author. Surgical technique is on high level and deserves admirations.

I agree in full with conclusions drawn. I believe that the algorithm, developed by Dr. Hristov will find its place in the orthopedic praxis in cases of PHFx treatment.

In chapter "Discussion" one can find answers to a large number of questions regarding treatment of PHFx. Potentials and disadvantages of PMMA augmentation have been analyzed and compared to BA augmentation. The author has performed a detailed comparison with published data in scientific literature sources. X-ray results' observation has been done as well. The author logically draws the statement that PMMA augmentation is a reliable tool for achieving a stable fixation and low rate of secondary dislocation. Prediction factors on PHFx complications have been presented thoroughgoing. Complications have been correctly separated in implant-related and non-implant related. The author deals in details with a number of publications, compared to his own results and position. The major cases for fixation failure have been concluded based on the indications for augmentation of these fractures.

In 86,4% of the fracture cases anatomical reposition has been achieved, which is a prove for a good operative technique. All fractures have healed. Follow ups of patients is performed accurately. Intraoperative average neck-shaft angle (NSA) in all cases is 130.61°. 12 months after operation- 126.67°. In fractures cases without augmentation in 64 patients a secondary dislocation with change in NSA from 129.6° to 125.68° has occurred and in augmentation cases respectively from 131.8° to 127.7°. In augmentation cases with BA NSA changes from 135° to 124.6°. In the target group with PMMA augmentation no statistically significant difference (p=0.011) has been recorded. This actually justifies Dr. Hristov's hypothesis, that PMMA augmentation allows to achieve strengthening of the osteosynthesis and better stability. Recorded functional results are comparative to literature records. Groups with augmentation have statistically significant difference after the 12 month period in relative CMS (p= 0.0002) and show better outcome compared to groups without augmentation. PMMA augmentation is statistically significant (p<0.05) and shows better functional results only in 3 and 6 months follow up period. After this timeframe there is no significant difference in both augmentation subgroups. Complications occurred have been accurately described and are comparable as percentage with several scientific publications. The scientific value of the research paper is solidified by the conducted statistic data analysis.

By Assoc. Prof. Dr. Kalin Kolev Mihov, Ph. D.

POSITION

With reference to: Dissertation paper "Operative treatment of proximal humeral fractures by locking plate with and without augmentation-comparative analysis"

For awarding the educational and scientific Doctorate degree / Ph.D./

By Order Nr. RD-26-523/ 14.02.2022 by the Director of UMHATEM N.I.Pirogov EAD I have been appointed as a member of Scientific Jury and assigned to provide a position about the procedure for awarding educational and scientific Doctorate degree /Ph.D. to the candidate Dr. Stoyan Hristov, doctorate candidate on individual doctorate program in scientific specialty "Orthopedics and Traumatology".

Proximal humeral fractures` epidemiology has been showing a tendency for increasing the number of such fractures within elderly population. Author's observation for the period of 30 years in Finland indicates a 4 quadruple growth of fractures within women over 80 years. Besides we observe a significant rise in patient's demands regarding treatment and life quality. Locking plate (LP) use in last 30 years broadened the indications for treatment for such fractures. However, results display significant frequency of complications reaching up to 49% - such as improper bone healing (mal-union), AVN, screw penetration and sub-acromial impingement. This comes only to show that stable fixation in cases of proximal humeral fractures (PHFx) with bone deficiency and complicated morphology is hardly achievable. In such situations the augmentation of the osteosynthesis by LP in PHFx is a reasonable option for ensuring stability of the construction.

The dissertation paper of Dr. Stoyan Hristov is focused on the analysis of fixation methods of PHFx by LP with or without augmentation.

Within the frame of the conducted research the author manages to optimize his approach in PHFx cases analyzing mistakes in treatment and intraoperative strategy` choice, improving the algorithm in order to avoid possible complications. The author pays attention to the difficulties in anatomical restoration, resulting from additional comminution in high - energy fractures or poor bone quality and expressed osteoporosis. Above circumstances increase the demands for osteosynthesis stability and focus our attention on the augmentation potentials, giving the author the option to compare techniques, recovery, functional outcome and complication in the three subgroups of patients with PHFx.

The author represents the opinion that reducing the stress on the medial wall of the proximal humerus enhances the primary stability of the fixation since the augmentation additionally recoups the poor bone quality and evenly distributes the load over the entire screw length- a thesis, which is justified by achieved functional results and analyses of postoperative complications` distribution.

Interpreting the middle - term results the author manages to formulate several scientific conclusions regarding the complete approach in PHFx cases and to draw the final conclusion that PMMA augmentation in PHFx with bone deficit ensures better results compared to treatment by LP only and comparable or better than treatment by LP and bone autograft (BA) augmentation.

The dissertation paper is structured in compliance with the requirements, demonstrates a logical consistency, and enclosed is a comprehensive list of literature sources, related to the problems with diagnostic, operative treatment of PHFx and results of its implementation.

Literature review includes 43 pages and is separated in six chapters. Based on first five chapters the author delivers a detailed analysis of surgical anatomy and biomechanics of shoulder joint, diagnostics and classification of humeral fractures, which is absolutely necessary for the analysis of problems related to treatment of PHFx. The last chapter's topic lies on non-operative and operative treatment, the main focus is on the type of fracture fixation and the necessity for augmentation in such treatment cases.

The dissertation author analyses in details the available surgical techniques for treatment of PHFx – their respective advantages and disadvantages. In my opinion this is the very first scientific research, which purposefully observes PHFx cases, treated by LP and PMMA augmentation in the metaphyseal zone. The dissertation goal is clearly formulated and four achievable tasks have been assigned.

In chapter **Patients and methods** the author separates patients according several characteristics and excluding criteria as well, including patients with 3- and 4- fragment fractures, treated by LP. General number of patients includes 112 cases with 114 fractures of proximal humerus for the period of four years, all of them fresh fracture cases. Observed number of patients is entirely sufficient for formation of studied groups and for statistical analysis of the results. Dr. Stoyan Hristov himself has been personally involved in the treatment of all patients included in this dissertation work. Criteria used for comparative analysis and patient groups in this research are clearly and precisely formulated, which proves the study statistically and scientifically feasible.

Complications in the observed group have been accurately recorded and carefully analyzed- within whole cohort 41 (36%) patients are with complications and the biggest percentage with complications (14%) are caused by cutting, screw penetration and loosening. Other significant complication frequency (8%) is related to secondary dislocation in varus. Author's research states that PMMA augmentation in PHFx cases with bone deficit ensures better treatment results compared to treatment by LP only and comparable or better than treatment by LP and BA augmentation.

The Discussion chapter includes 23 pages and is actually a critical analysis of author's results compared to results of proven authors.

Conclusions, drawn by the author, are clearly formulated and logically justified based on in – depth analysis on the problematic issue.

1. Stability of the construction via PMMA augmentation is better and reduces the risk of penetration and secondary varus dislocation of the fracture.
2. Patients with augmentation achieve faster and better functional outcome.
3. PMMA augmentation could replace BA as treatment method based on short operating time ($p < 0.01$) and decreased percentage of complications. In the 3rd and 6th postoperative period a better CMS & DASH compared to BA augmentation is statistically significant ($p < 0.05$).
4. A correlation dependency and positive correlation coefficient between indexes of postoperative neck-shaft angle (NSA) and functional outcome, expressed by CMS, $p = 0.0292$, $\alpha < 0.05$ has been recorded.
5. The author has developed an action algorithm in treatment of PHFx aiming to optimize and facilitate the approach to patients in order to minimize treatment complications.

Literature bibliography is in alphabetical order and includes 251 scientific sources, no presence of Bulgarian authors is noticeable.

Following contributions in the dissertation paper, presented by Dr. Stoyan Hristov are clearly to be considered:

1. The author has conducted a detailed analysis of indications for augmentation in treatment of PHFX and clinical and biomechanical aspects of both methods of osteosynthesis augmentation by LP.
2. For the first time in Bulgaria a research is presented, which purposely follows PHFX cases, treated by LP and PMMA augmentation in metaphyseal void.
3. Based on middle – term results the PMMA augmentation is justified to be used in bone-preserving operations of PHFX.
4. Recorded data display better functional and X-ray results in PHFX, operated by LP and augmentation.

In conclusion I would like to point out that the dissertation paper fulfills all criteria, required for obtaining the scientific-educational Doctorate degree / Ph. D.

I give a positive assessment on the presented paper and encourage the members of the Scientific Jury to award Dr. Stoyan Hristov the educational and scientific Doctorate degree / Ph. D.

23.03.2022

Assoc. Prof. Kalin Mihov, Ph. D.