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Expandable intramedullary nail – experimental biomechanical evaluation

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ABSTRACT

Purpose: The paper presents results of experimental analysis of femur and femur – expandable intramedullary nail system. The aim of the work was to determine displacement in three models. In addition, the torsion of the system aiming at determining the moments depending on the torsional angle of the bone was carried out.

Design/methodology/approach: Three femurs were selected for studies. The analysis was carried out on the femur – expandable intramedullary nail system. The influence of the loads and displacements on the bone – nail system on the results of experimental analysis was analysed. In order to carry out calculations, three models were selected: model I – bone without fracture gap, model II and III – femur with expansion intramedullary nails – fracture gap was located 100 mm under greater trochanter. The studies were performed on femur models produced by Swedish company Sawbones. The intramedullary „Fixion IM" nails (Ti-6Al-4V alloy) were implanted into the bone. Displacements of determinated models were being recorded from the sensors every 100 N from 10 N to 2000 N.

Findings: The analyses showed the difference in displacements, depending on the selected models.

Research limitations/implications: The limitations were connected with simplification of boundary conditions during analysis which were the result of the simplification of the models. While studying, muscles and ligaments supporting the bone in anatomic position were not taken into consideration. Instead, the system has been loaded with the axial force (compression).

Practical implications: The obtained results can be useful in clinical practice. They can be applied in selection of stabilization methods or rehabilitation as well as in describing the biomechanical conditions connected with type of bone fracture obtained from medical imaging.

Originality/value: . The work compares the values of displacement of characteristic points of femur (healthy – model I) with the femur – expandable intramedullary nail system (models II and III) with the applied force. In order to estimate the value of the torsional angle of the upper part in relation to the lower one depending on the applied force, the torsion of the model was conducted. On this basis, it was indicated a maximum moment in which the nail would not become loose in medullar canal.

Keywords: Experimental analysis; Biomechanical analysis; Biomaterials

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METHODOLOGY OF RESEARCH, ANALYSIS AND MODELLING

1. Introduction

In last few years along with the dynamic development in science, a significant progress in medicine was made. The growing demand for biomaterials and at the same time decreasing age of users make medicine constantly improve its achievements, and that is further costs reduction, onerousness and time of treatment.

The complexity of the bionics of movement and implant's behaviour in a tissue environment requires materials of particular properties. A tissue environment containing chlorides creates very good conditions for corrosion; what is more, variable loads increase its risk.

Metallic biomaterials have found wide application in reconstructive surgery of skeleton thanks to its useful mechanical properties and good biocompatibility [1-18].

It is known that structural form of nail elements and properties of biomaterial have crucial influence on the stiffness of the nail – bone fragments system, on which final quality of stabilization and bone adhesion are dependant.

These issues are currently solved on the basis of electromechanical effects occurring in a bone and stimulating osseous tissue formation and its histogenesis in particular stages of formation.

From clinical point of view modern nails broaden the area of its usage, they make operations easier and faster and, as a result, they should ensure better condition of bone adhesion.

In a group of issues connected with searching for new solutions of structural intramedullary nails those predominate aiming at [19]:

- minimizing the invasion of the operation in both, the procedure of implanting the nail and its removing,
- reducing the time of operations, which is connected with reducing the time of radiation and saving the time of operators and the equipment used during procedure,
- reducing blood loss during and after procedure,
- reducing reactivity,
- reducing the time of treatment and hospitalization,
- reducing the risk of clots,
- increasing patient's comfort, making the procedure easier.

Healing of long bone fractures is connected with a high risk of complications; therefore, it is really important to choose good method of treatment.

Application of a new expansion "Fixion IM" nails has become very popular, revolutionary, effective, simple and minimally invasive procedure for the treatment of long bone diaphyseal fractures treatment of long bone fractures. Application of these systems eliminates the need for interlocking screws [20-25].

In many types of solutions it is worth pointing out one which involves most of mentioned evolutionary aspects of intramedullary nails, and that is so called self-expandable system stabilizing intramedullary fractures of long bones fixion – Fig. 1.

This nail is Cr-Ni-Mo stainless steel tubes strengthen by four longitudinal crosspieces.

The nail is finished in distal end of the femur - tapered, whereas in proximal end of the femur it has one-way valve.

The structure of this type is axially compressed and after introducing it into medullar canal without the necessity of drilling and introducing guide it is expanded with saline solution pumped inside the nail at the pressure of 70 atmospheres. The nail after expanding adjusts to the geometry of medullar canal and the transversal strengthening effectively, in the opinion of the authors' of the solution, blocks the implant in medullar canal. The maximum expansion of diameter is 175% [19].

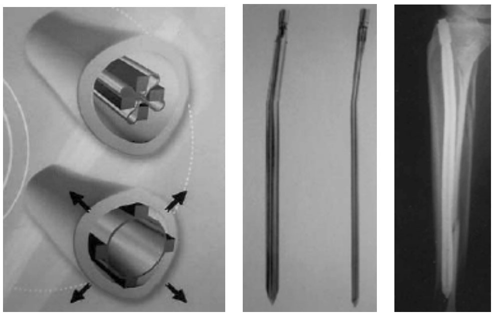


Fig. 1. Fixion intramedullary nail before and after expansion [19]

Intramedullary nailing has become a standard procedure for the treatment of closed fractures of long bones. The Fixion system consists of an expandable, cylindrical tube, of a conical shaped distal end. With expansion the nail increases its diameter and locks into an anatomical fit into the bone. Intramedullary interlocking nailing has become the gold standard in treatment of closed diaphyseal fractures of long bones. Being closer to the weight-bearing axis, an intramedullary nail has mechanical advantages over other fracture stabilization devices, such as plates, external fixators, casts, etc. – Fig. 2 [22].

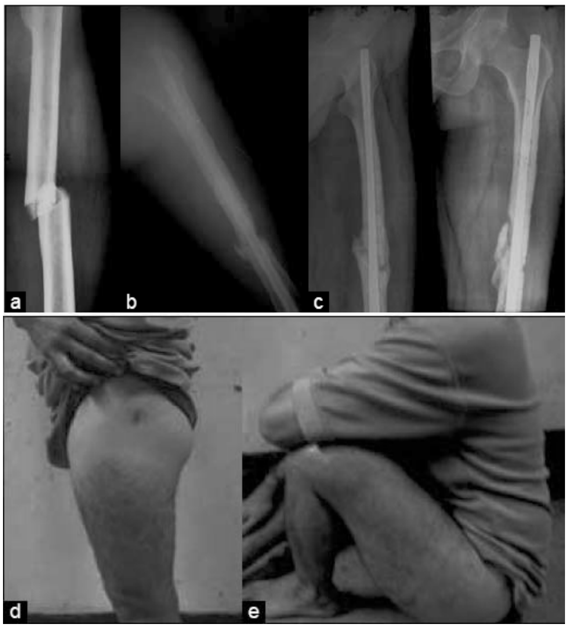


Fig. 2. Preoperative anteroposterior X-ray of thigh showing a transverse fracture soft femur – a, Post-operative antero-posterior X-rays of thigh showing well aligned fracture with intramedullary expandable nail – b, Anteroposterior and lateral view follow up X-rays showing fracture union – c, Clinical result at follow up showing good functional outcome – e, d [26]

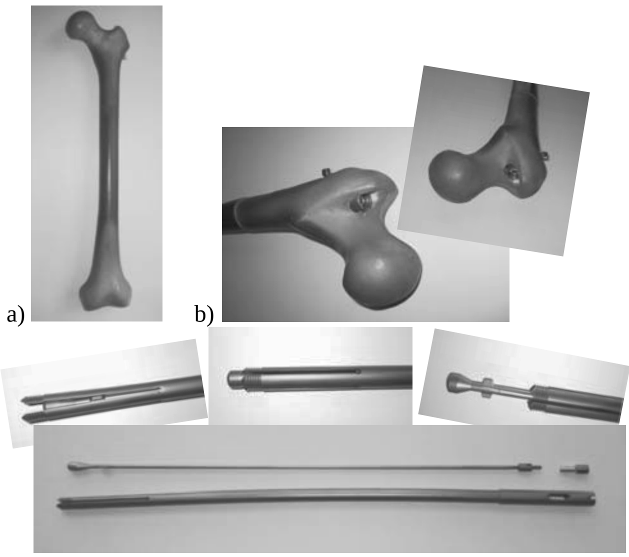
2. Material and methods

Three femur – expandable intramedullary nails system were applied in experimental investigations. Studies was performed on femur models produced by Swedish company Sawbones The interior of the bone consists of foamy marrow and the exterior layer is covered with short glass fibres with epoxy resin. Models were specially designed to reproduce physical properties of human bones [27].

The intramedullary „Fixion IM” nails (Ti-6Al-4V alloy) were implanted in to the bone – Fig. 3. The nail consists of the upper part which is blocked by a screw in order to unable its rotation during anatomic load on the limb, and the lower part which is represented by expandable ending, which enables attaching the nail in medullar canal.

In order to compare characteristic displacements, a biomechanical analysis of three models was carried out:

- Model I – femur without fracture gap – Fig. 3a,
- Model II, III – femur with expansion intramedullary nails – fracture gap was located 100 mm under greater trochanter – Fig. 3b.



a) b) c)

Fig. 3 Model of the femur – a, top view – b expansion intramedullary nail – c

In order to place examined bone in the grip, it has been immobilized in epoxy resin.

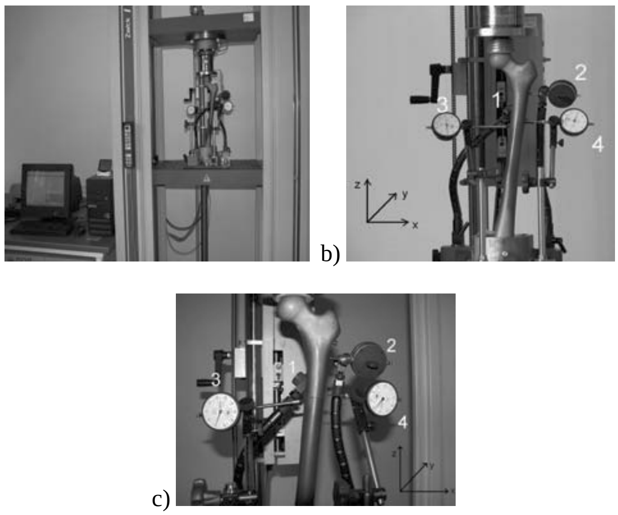
Before immobilization the bone was set so that it reproduces the anatomic position in human skeleton.

The bone was filled with epoxy rinse Epidian 5 with hardening agent Z-1 – Table 1. Before filling the bone with the resin it was mixed up with appropriate amount of hardening agent.

The tests of the femur – expansion intramedullary nails system were carried out with the use of the test machine Zwick/Roell Z100/SN5A. The sensors recorded displacements in the frontal (x direction – sensors 2, 3, 4) and sagittal (y direction – sensor 1) plane. Additionally, displacements in „z” direction were registered – Fig. 4. Displacements were being recorded by the sensors every 100 N from 10 N to 2000 N.

Table 1.
The properties of Epidian 5 resin

Form	highly viscotic liquid
Colour	light yellow
Epoxy equivalent	196 – 208
Density in 20ºC	1.18 – 1.19 kg/dm^3
Viscosity in 25ºC	20000-30000 mPas
Contraction in the hardening time	1%



a) b) c)

Fig. 4. Displacement sensors structure: a – test machine, b – femur without fracture gap, c – femur – expandable intramedullary system

During the anatomic loading a torsion occurs in the femur, which is the result of torsional moment. In order to get its value depending on the torsional angle of the upper bone fracture in relation to the lower one, during the analysis the torsion of the system was carried out with the maximum strength F=2000 N loading on the head of femur. The stand for studies and separate stages of the torsion of the bone is shown on Figs. 5 and 6.

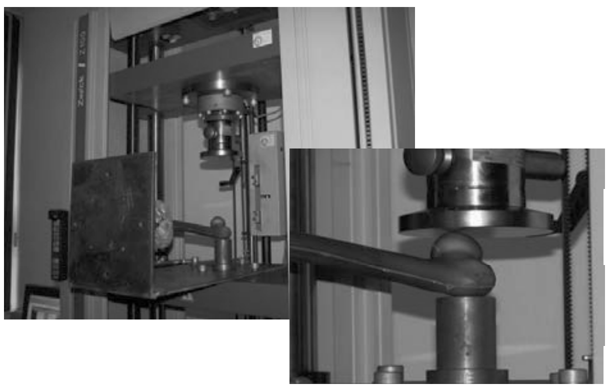


Fig. 5. A stand for torsion of the bone – nail system

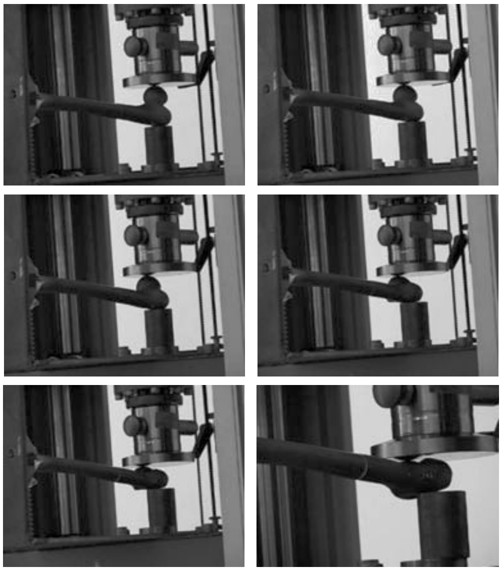


Fig. 6. Stages of the torsion of the bone – nail system

Obtained results will enable to estimate the torsional angle in which the attached part sliding of the nail in medullar canal takes place. The results are significant if we take the application of this type of nails into consideration in femoral shaft fracture in adults.

3. Results

Comparison between models I, II I III are presented in the Tables 2-4 and Figures 7-11. These figures show displacement from the sensors I, II, III and IV (x and y) and vertical direction (z – 0) for three chosen models.

On the basis of the obtained results, it can be stated that: maximum value of displacements were located in fracture gap for lower fragment (frontal plane) and were equal for Model: I – -1.86 mm, II – -2.89 mm and III – -2.15 mm, the obtained values did not exceed acceptable displacement (3 mm), assuring correct bone union (sensor III, axis x). Minimum value of displacements was located in sagittal plane and was equal for Model: I – 0.08 mm, II – -0.44 mm and III – -0.27 mm (sensor I, axis Y). In the femur – expansion intramedullary nail system, a similar value of displacement of fragments in typical point of femur without fracture gap was observed and it was equal to sensor 1 – -0.32 mm for Model I, -0.44 mm for Model II i -0.27 mm and Model III, stiffness of the both femur – nail system and the unbroken were similar. The value of displacement for sensor II – axis x, was equal: 1.9 mm for Model I, 0.48 mm for Model II and 1.65 mm for Model III.

Table 2.
Results of the experimental analysis - the values of displacement of Model I characteristic points

		Force F, N	0	100	300	500	700	900	1100	1300	1500	1700	1900	2000
Model I	Displacement, mm	Sensor 1	0	0.01	0.10	0.22	0.31	0.38	0.44	0.45	-0.44	-0.40	-0.37	-0.32
		Sensor 2	0	0.03	0.13	0.28	0.46	0.64	0.82	1.00	1.21	1.44	1.75	1.94
		Sensor 3	0	-0.05	-0.17	-0.32	-0.47	-0.55	-0.80	-0.97	-1.17	-1.39	-1.69	-1.86
		Sensor 4	0	0.07	0.19	0.35	0.51	0.68	0.86	1.06	1.27	1.53	1.88	2.12

Table 3.
Results of the experimental analysis - the values of displacement of Model II characteristic points

		Force F, N	0	100	300	500	700	900	1100	1300	1500	1700	1900	2000
Model II	Displacement mm	Sensor 1	0	-0.11	-0.08	-0.08	-0.08	-0.08	-0.08	-0.10	-0.12	-0.13	-0.18	-0.44
		Sensor 2	0	0	0.13	0.22	0.29	0.31	0.33	0.35	0.37	0.38	0.39	0.41
		Sensor 3	0	-0.04	-0.25	-0.46	-0.68	-0.90	-1.10	-1.31	-1.56	-1.82	-2.20	-2.89
		Sensor 4	0	0.01	0.07	0.22	0.32	0.40	0.46	0.52	0.58	0.63	0.68	0.78

Table 4.
Results of the experimental analysis - the values of displacement of Model III characteristic points

		Force F, N	0	100	300	500	700	900	1100	1300	1500	1700	1900	2000
Model III	Displacement mm	Sensor 1	-0.06	-0.08	-0.10	-0.11	-0.11	-0.11	-0.11	-0.12	-0.15	-0.19	-0.24	-0.27
		Sensor 2	0	0.01	0.17	0.35	0.52	0.68	0.85	0.99	1.14	1.30	1.48	1.57
		Sensor 3	0	-0.05	-0.27	-0.53	-0.76	-0.98	-1.19	-1.40	-1.60	-1.80	-2.03	-2.15
		Sensor 4	0	0.04	0.27	0.53	0.78	1.01	1.24	1.44	1.65	1.86	2.06	2.14

Low values of displacement of lower fragment were a result of too stiff fastening of examined models in further part of the bone. After conducted studies a deformation of the upper screw in a place of its joint with the nail was observed, which is confirmed by stress values obtained during conducted earlier numerical analysis of femur – expandable nail system – Fig. 12. Maximum values of stresses and deformations occurred similarly, like in the case of experimental studies in a place of a screw joint with a nail.

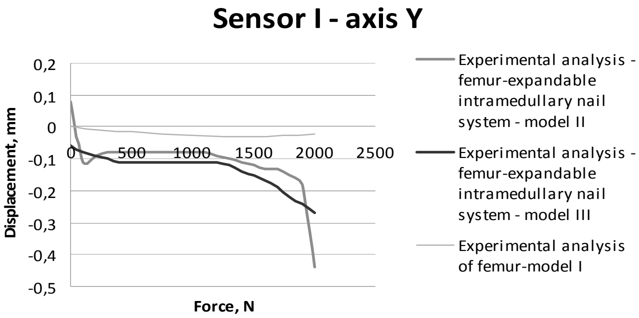


Fig. 7. Displacements in the y direction as a function of loading for Models I, II and III for clock sensor 1

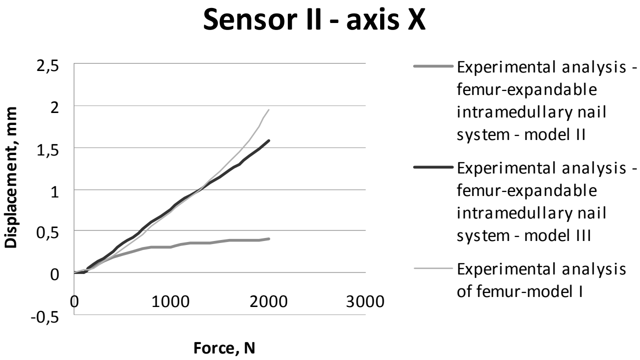


Fig. 8. Displacements in the x direction as a function of loading for Models I, II and III for clock sensors 2

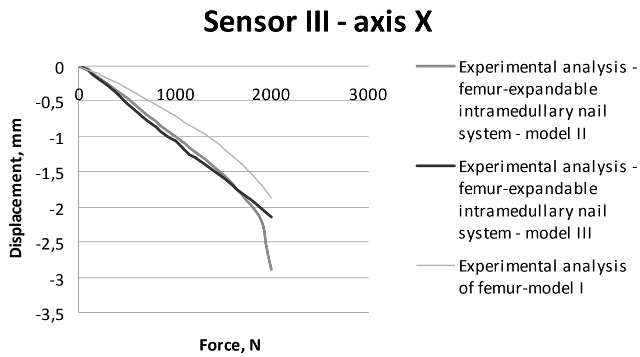


Fig. 9. Displacements in the x direction as a function of loading for Models I, II and III for clock sensors 3

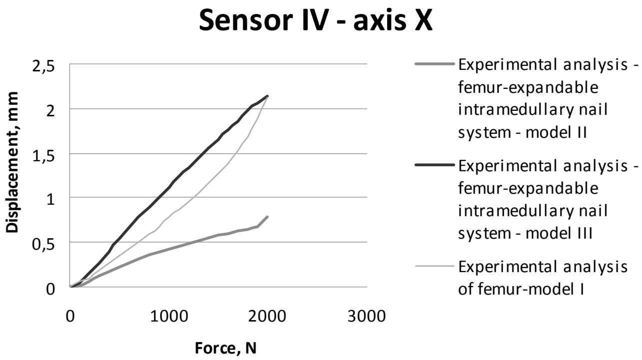


Fig. 10. Displacements in the x direction as a function of loading for Models I, II and III for clock sensors 4

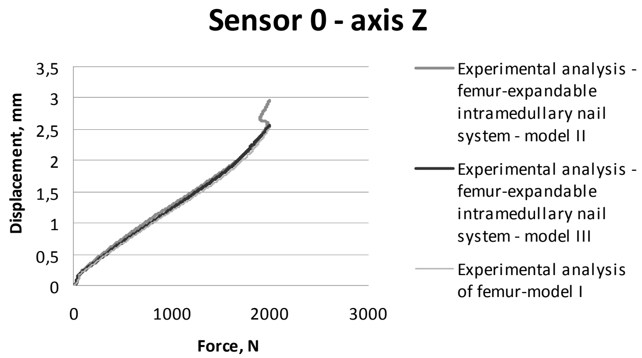


Fig. 11. Displacement in a vertical direction (z)

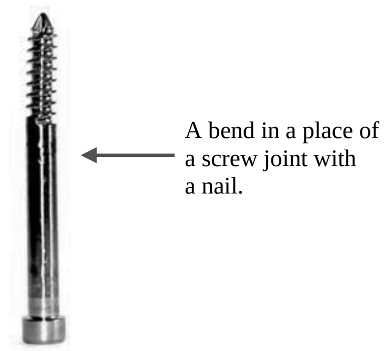


Fig. 12. Screw after the studies of femur – expandable nail system

During the analysis, depending on the applied compression force and torsional angle of the bone, torsional moments adequate to separate stages of the rotation of the head of the bone was calculated – Table 5, Figs. 13-16.

On the basis of conducted studies it can be stated that with torsional angle φ about 10° there has been first significant decrease of the registered value of the torsional moment from 7 Nm to 5 Nm in Model II and from 16 Nm to 13 Nm in Model III was observed, which can prove that such a torsional angle can initiate sliding of the expandable part of the nail in medullar canal.

For bigger values of torsional angles, the values of moments M were increasing appropriately for Model 2 up to 12 Nm, for Model III up to a value of 27 Nm with a torsional angle of about 18°. As a result of those exceeded values the expandable part of the nail started to become totally loose and began sliding in medullar canal.

Table 5.
Results of experimental analysis - torsion of the bone – nail system

Force F, N	Moment M, Nm	Angle displacement, φ,°
0	0	0
-1.05E+00	-0.044	0.002
1.67E+02	7.001	1.801
2.50E+02	10.509	3.600
3.08E+02	12.924	5.400
3.42E+02	14.384	7.201
3.70E+02	15.544	9.000
4.00E+02	16.792	10.800
4.62E+02	19.412	12.601
5.43E+02	22.824	14.400
5.97E+02	25.092	16.200
5.67E+02	23.830	18.001
6.18E+02	25.965	19.800
6.51E+02	27.331	21.601
6.41E+02	26.934	23.401
6.39E+02	26.824	25.200
6.51E+02	27.345	27.001
6.57E+02	27.609	28.800
6.46E+02	27.147	30.600
6.61E+02	27.742	32.401
6.66E+02	27.962	34.200
6.77E+02	28.417	36.000
6.56E+02	27.543	37.801
6.31E+02	26.494	39.600
5.96E+02	25.011	41.400
5.86E+02	24.593	43.201
5.66E+02	23.793	45.000

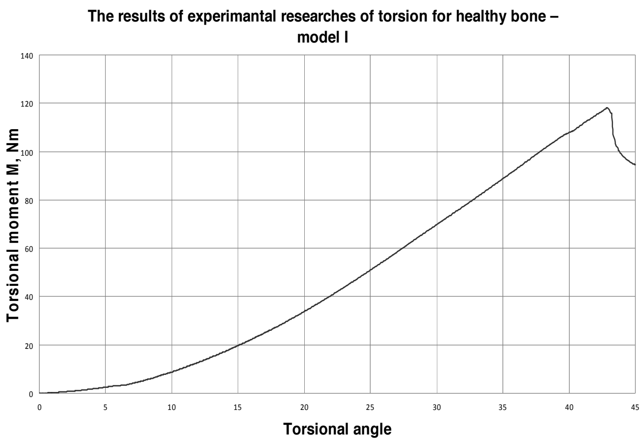


Fig. 13. Torsional moment M depending on the torsional angle of the heady of femur φ,° (Model I)

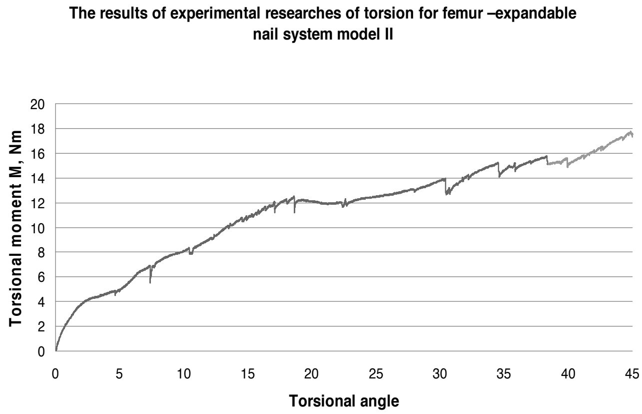


Fig. 14. Torsional moment M depending on the torsional angle of the heady of femur φ,° (Model II)

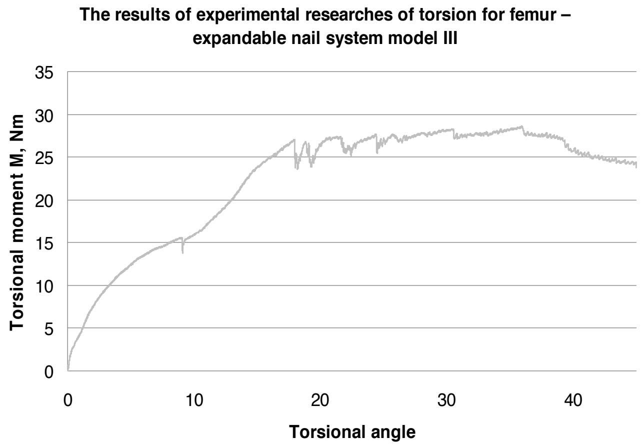


Fig. 15. Torsional moment M depending on the torsional angle of the heady of femur φ,° (Model III)

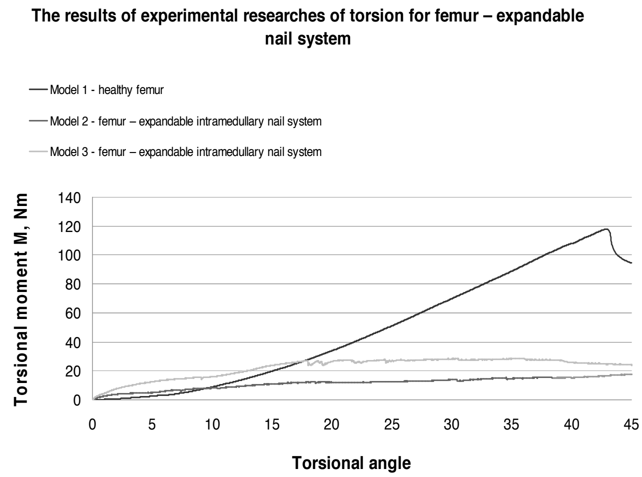


Fig. 16. Comparison of torsional moments M in torsional angle φ,° function for Models I, II and III

4. Conclusions

Currently, to stabilize proximal femur in adults elastic methods of osteosynthesis are promoted. The basic aim of these methods is to provide micro movements of bone fragments that stimulate remodelling of bone by differentiation of its structure starting from granulation tissue through fibrous and cartilaginous tissue up to a primeval structure of bone.

On the basis of conducted biomechanical studies of chosen models it can be stated that the character of the curves obtained during the compression was similar. It proves that a fractured bone with intramedullar nail implanted is distinguished by stiffness similar to healthy bone (without simulated fracture).

Taking into consideration the fact that maximum values of displacement in characteristics points of models do not exceed acceptable values of 3mm, a conclusion can be drawn that the origin of tissue regeneration in a place of fracture will proceed in a proper way. However, the results of earlier conducted studies show that in a place of a joint of the upper screw with a nail there is an accumulation of stress, which has been confirmed in laboratory studies, since the bolt became loose and bent.

The effect was confirmed also by doctors who maintain that in some specific load conditions the screw is deformed.

Conducting the torsion of the system it helped to achieve torsional values depending on the torsional angle of the upper part in relation to the lower one.

Obtained results show that at low values of torsional angle, the expandable part becomes loose and starts sliding in medullar canal. In order to achieve better stabilization of the system, the structure of the nail must be changed by enlarging the contact area between the nail and the walls of medullar canal.

References

[1] A. Krauze, W. Kajzer, W. Walke, J. Dzielicki, Physicochemical properties of fixation plates used in pectus excavatum treatment, International Journal of Computational Materials Science and Surface Engineering 1/3 (2007) 351-365.

[2] J. Żmudzki, W. Walke, W. Chladek, Influence of model discretization density in fem numerical analysis on the determined stress level in bone surrounding dental implants, in: Information Technologies in Biomedicine, Advances in Soft Computing 47, Springer-Verlag, Berlin Heidelberg, 2008, 559-567.

[3] M. Kiel, J. Marciniak, M. Basiaga, J. Szewczenko, Fatigue analysis of transpedicular stabilizer on lumbar part of spine, Engineering of Biomaterials 12/89-91 (2009) 237-239.

[4] W. Walke, Z. Paszenda, J. Filipiak, Experimental and numerical biomechanical analysis of vascular stent, Journal of Materials Processing Technology 164-165 (2005) 1263-1268.

[5] Z. Paszenda, M. Basiaga, FEM analysis of drills used in bone surgery, Archives of Materials Science and Engineering 36/2 (2009) 103-109.

[6] A. Krauze, J. Marciniak, A. Marchacz, Biomechanical analysis of plates used in treatment of pectus excavatum, Archives of Materials Science and Engineering 28/5 (2007) 301-304.

[7] M. Kiel, J. Marciniak, J. Szewczenko, M. Basiaga, W. Wolański, Biomechanical analysis of plate stabilization on cervical part of spine, Archives of Materials Science and Engineering 38/1 (2009) 41-47.

[8] J. Żmudzki, W. Walke, W. Chladek, Stresses present in bone surrounding dental implants in FEM model experiments, Journal of Achievements in Materials and Manufacturing Engineering 27/1 (2008) 71-74.

[9] M. Kaczmarek, J. Marciniak, J. Szewczenko, A. Ziębowicz, Plate stabilizers in elastic osteosynthesis, Proceedings of the 11th International Scientific Conference "Contemporary Achievements in Mechanics, Manufacturing and Materials Science" CAM3S'2005, Gliwice−Zakopane, 2005, 436-443.

[10] J. Marciniak, J. Szewczenko, W. Walke, M. Basiaga, M. Kiel, I. Mańka, Biomechanical analysis of lumbar spine stabilization by means of transpedicular stabilizer, in: Information Technologies in Biomedicine, Advances in Soft Computing 47, Springer-Verlag, Berlin Heidelberg, 2008, 529-536.

[11] W. Kajzer, J. Marciniak, Experimental and FEM analysis of urological stents. Engineering of Biomaterials 10/65-66 (2007) 57-59.

[12] A. Krauze, J. Marciniak, Numerical method in biomechanical analysis of intramedullary osteosynthesis in children, Journal of Achievements in Materials and Manufacturing Engineering 15 (2006) 120-126.

[13] W. Chrzanowski, J. Marciniak, Biomechanical analysis of the femoral bone – interlocking intramedullary nail system, Proceedings of the 18th European Conference "Biomaterials", Stuttgart, 2003, 154.

[14] J. Marciniak, W. Chrzanowski, M. Kaczmarek, Biomechanical analysis of femur-intramedullar nail system with the use of finite element method, Biomaterials Engineering 6/30-33 (2003) 53-55.

[15] W. Chrzanowski, J. Marciniak, Biomechanical and biomaterial conditions in intramedullar osteosynthesis, Proceedings of the 3rd Scientific Conference "Materials, Mechanical and Manufacturing Engineering" MMME'2005, Gliwice−Wisła, 2005, 319-324.

[16] A. Krauze, J. Marciniak, Numerical method in biomechanical analysis of intramedullary osteosynthesis in children, Proceedings of the 11th International Scientific Conference "Contemporary Achievements in Mechanics, Manufacturing and Materials Science" CAM3S'2005, Gliwice−Zakopane, 2005, 528-533.

[17] M. Kaczmarek, J. Marciniak, Issues of plate stabilizers for osteosynthesis, Proceedings of the 3rd Scientific Conference "Materials, Mechanical and Manufacturing Engineering" MMME'2005, Gliwice−Wisła, 2005, 325-334.

[18] W. Walke, Z. Paszenda, W. Jurkiewicz, Numerical analysis of three – layer vessel stent made form Cr-Ni-Mo steel and tantalum, International Journal of Computational Materials Science and Surface Engineering 1/1 (2007) 129-139.

[19] J. Marciniak, W. Chrzanowski, A. Kajzer, Intramedullary nailing in osteosynthesis, Printing House of the Silesian University of Technology, Gliwice, 2008, 15-120 (in Polish).

[20] A. Kajzer, W. Kajzer, J. Marciniak, Osteosynthesis with the use of expansion intramedullary nails, Engineering of Biomaterials 11/77-80 (2009) 74-76.
[21] W. Kajzer, A. Krauze, M. Kaczmarek, J. Marciniak, FEM analysis of the expandable intramedullary nail, in: Information Technologies in Biomedicine, Advances in Soft Computing 47, Springer-Verlag, Berlin Heidelberg, 2008, 537-544.
[22] S. Lepore, N. Capuano, L. Lepore, P. Jannelli, Clinical and Radiographic Results with the Fixion Intramedullary Nails: An Inflatable Self-Locking System for Long Bone Fracture, OsteoTrauma Care 10 (2002) 32-35.
[23] S. Lepore, N. Capuano, L. Lepore, G. Romano, Preliminary clinical and radiographic results with the Fixion intramedullary nail: an inflatable self-locking system for long bone fractures, Journal of Orthopaedics and Traumatology 3 (2000) 135-140.
[24] E.L. Steinberg, N. Blumberg, S. Dekel, The fixion proximal femur nailing system: biomechanical properties of the nail and a cadaveric study, Journal of Biomechanics 38 (2005) 63-68.
[25] G. Panidis, F. Sayegh, A. Beletsiotis, D. Hatziemmanuil, K. Antosidis, K. Natsis, The Use of an Innovative Inflatable Self-Locking Intramedullary Nail in Treating and Stabilizing Long Bone Fractures. Technique-Preliminary Results, OsteoTrauma Care 11 (2003) 108-112.
[26] S.K. Kapoor, H. Kataria, T. Boruah, S.R. Patra, A. Chaudhry, S. Kapoor, Expandable self-locking nail in the management of closed diaphyseal fractures of femur and tibia, Indian Journal Orthopaedic 43/3 (2009) 264-270.
[27] A. Kajzer, W. Kajzer, J. Marciniak, Numerical and experimental analysis of the new, expansion intramedullary nail, Engineering of Biomaterials 12/89-91 (2009) 115-118.