ISSN 2304-3415, Russian Open Medical Journal
2016. Volume 5. Issue 2. Article CID e0206
DOI: 10.15275/rusomj.2016.0206

Review article

Expandable intramedullary nail: review of biomechanical studies

Dmitry Ivanov [1], Anatoly Barabash [2], Yuri Barabash [2]

[1] Saratov State University n.a. N.G.Chernyshevsky, Saratov, Russia
[2] Saratov Scientific Research Institute of Traumatology and Orthopedics, Saratov, Russia

Received 4 May 2016, Accepted 18 May 2016

Abstract: This article reviews studies of Fixion expandable nail biomechanical properties in case of long bones fractures osteosynthesis. The purpose of this study was to systematize biomechanical researches dedicated to the expandable nail. There were found seven biomechanical studies published between 2005 and 2008. Among them, six studies are devoted to mechanical experiments, and one is a comment to the published study. In four papers, the authors compared biomechanical properties of expandable and locked nails.
Expandable nail proved to be a highly effective device for fixation of long bone fractures. However, in case of mid-shaft fractures Fixion nail was significantly less stable than standard locked nails. This conclusion was obtained for humeri, tibia and femur. Stiffness of bone-implant system for expandable nail in case of torsional loads was significantly lower than the similar parameter of standard implant in case of transverse fracture models.
Expandable Fixion nail rod should be used with great caution for osteosynthesis of long bones transverse shaft fractures. In contrast, in the case of oblique and spiral fractures, when contact area between fragments is sufficiently high and can share loads between nail and bone fragments, the expandable nail should be used.

Keywords: Fixion nail, expandable nail, locked nail, intramedullary nail, biomechanics

Cite as Ivanov D, Barabash A, Barabash Y. Expandable intramedullary nail: review of biomechanical studies. *Russian Open Medical Journal* 2016; 5: e0206.

Correspondence to Dmitry Ivanov. Address: 83, Astrakhanskaya str., Saratov, Russia. Tel.: +79173146807. E-mail: ivanovdv@gmail.com

Introduction

Fixion nail (CarboFix Orthopedics Ltd, Tel Aviv, Israel) was introduced into clinical practice in 1999. Many clinical studies and several reviews have shown its high success in long bone fracture osteosynthesis [1-4]. First article [5] with clinical data on the use of Fixion nail was published in 2000. Expandable nail provides long contact area between nail ribs and endosteal surface therefore bone-nail system should be stable under influence of external loads. Moreover, as the reaming procedure and distal locking screws are not necessary in case of expandable nail installation, some more advantages over locked nails have been observed as a significantly lower duration of surgical operation, reduction in blood loss and lower radiation exposure to patient and surgeon. The new nail has proved to be an effective, simple, minimally invasive device for long bone fracture fixation.

Despite the fact that Fixion nail has been used in clinical practice for more than 15 years, we found only seven published articles aimed at its biomechanical properties investigation. Although there were published several retrospective investigations and systematic reports of clinical studies on this topic [1-3].

From the mechanical point of view Fixion nail is more preferable than locked nails. In fact, locking screws are stress concentrators which may lead to screw or nail breakage [6-8]. In addition, locking screws prevent load distribution between bone fragments, which negatively affect fracture healing and can lead to various complications [1]. Standard locked nails also need dynamization procedure.

Clinical practice suggests that expandable nail does not have disadvantages of locked nails. However, several works [9-11] showed that bone-nail system in case of Fixion nail installation wouldn't be as stable as system with locked fixator under influence of torsional loads.

The purpose of this work was to conduct a systematic review of biomechanical publications devoted to the study of the expandable Fixion nail. Particular attention was drawn to the rotational stability of the bone fragments fixation.

Table 1. Search keywords for published articles

№	*Keyword*
1	«biomechanics» AND «Fixion nail»
2	«biomechanical» AND «Fixion nail»
3	«biomech» AND «Fixion nail»
4	«biomechanics» AND «expandable nail»
5	«biomechanical» AND « expandable nail»
6	«biomech» AND « expandable nail»
7	«mechanics» AND «expandable nail»
8	«mechanical» AND « expandable nail»
9	«mechanics» AND «Fixion nail»
10	«mechanical» AND «Fixion nail»

Table 2. Biomechanical works which were carried out for the expandable nail

	Bone type	*Bone material (cadaveric, synthetic)*	*Bone quantity*	*Loads: type and value*	*№ in reference list*	*Note*
1	Tibia	Cadaveric	8 pairs	Bending deformation of 3 mm; axial force of 20 N force plus 1 N*m torsional moment; axial 150 N force plus torsional moment until 20 degree rotation	[2]	Comparison with locked Stryker nail
2	Femur (hip joint)	Cadaveric	3 bones	Axial 750 and 1500 N loads, each for 10000 cycles	[8]	Liquid acrylic cement instead of saline
3	Femur (proximal part)	Cadaveric	13 bones	From 98 to 980 N axial force for 1 million cycles; axial load of 400, 460 and 550 N; bending loading, pull-out loading	[14]	Additionally nails were investigated separately from bones
4	Femur	Cadaveric	10 healthy pairs and 10 osteoporotic pairs	Torsional moment of -1 to 10 N*m, frequency of 1 Hz, 5000 cycles	[11]	Two generations of Fixion nail. Comparison with locked T2 Stryker nail
5	Humeri	Cadaveric	8 pairs	Bending and torsional loadings	[3]	Comparison with locked Synthes nail
6	Tibia and humeri	Cadaveric	6 pairs of tibia and 6 pairs of humeri	Torsional moment +- 5 N*m for 4 preconditioning cycles and 1 for parameters evaluation.	[10]	Comparison with locked Zimmer nail

Material and Methods

We searched for articles published in English from 2000 to the end of 2015. Medline database was used as the main source of scientific papers on the subject under investigation. Advanced search has also been carried out in Cochrane library, as well as in Google Scholar system. Unpublished and grey literature was also searched with the help of OpenSINGLE (System of Information on Grey Literature in Europe). According to the keywords, which are presented in *Table* 1, we selected only seven articles devoted to biomechanics of Fixion nail.

From seven selected for the reviewing process articles six are dedicated to mechanical tests on universal testing machines [9-12, 14, 15] and one [13] is a letter to the editor with comments and questions on published work.

Results

All founded biomechanical articles were summarized in *Table* 2. The table shows that in terms of biomechanics expandable nail was investigated in relation to the femur (total 56 bones), tibia (28 bones) and humeri (28 bones). The authors investigated bone-nail systems under cyclic and static loading conditions. In four works [9-12] expandable nail was compared with standard locked nails.

Femur

The first article on biomechanics of the expandable nail was published in 2005 in Journal of Biomechanics [5]. This is the only one biomechanical article about Fixion nail which is listed on the official website of the nail manufacturer. The article deals with proximal Fixion nail, which was investigated in several stages. At first stage authors obtained bending stiffness and strength. The nail was subjected to a static load. Yield strength of 45 N*m was evaluated. This parameter of Synthes PFN (DePuy Synthes, USA) is 25 N*m. Then Fixion (3 samples) nail was subjected to a cyclic sinusoidal compressional loading between 98 and 980 N for 1 million cycles. The tip of hip peg passed this test with no indications of failure. Test of axial compression with loading rate of 5 mm/min was applied to hip peg tip. Average maximal bending force was 642±35 N (presented as mean and standard deviation – M±SD).

Further mechanical tests of the inserted nail into cadaveric femur were carried out. Bone-nail systems were investigated under axial loads of 400, 460 и 550 N. Peg deflection values were 3.2, 3.6 and 5.0 mm respectively. Hip peg pull-out tests were carried out for three Fixion nails and for one Smith and Nephew (Smith and Nephew, London, UK) hip screw. Maximal pull-out force for Fixion hip peg was 268.0±23.6 N and for Smith and Nephew hip screw it was 298.8 N. During torsion stability tests maximal torsional moment for Fixion nail was 128.9±8.1 Nm and 25.6 Nm for Smith and Nephew screw.

The last test – intraosseous pressure evaluation for 13 femoral heads during nail expansion. Average baseline intraosseous pressure was 3.84 (±3.5) mmHg (presented as mean and standard deviation) and it was increased after the expansion to 4.84 (±1.9) mmHg.

Kummer and coauthors [15] investigated expandable stem total hip replacement system. They used liquid acrylic cement instead of saline to expand the nail. They also subjected bone-nail systems to cyclic axial loading of 750 and 1500 N at 3 Hz frequency each for 10000 cycles. Authors researched three femur bones. Under considered loading cases expandable nail showed minimal displacements (between 0.02 and 0.14 mm). Expansion of the nail did not create high internal pressure applied to the bone medullary canal.

Two generations of Fixion nail were mechanically tested for 10 pairs of osteoporotic and 10 pairs of healthy femur bones [12]. Goal of the research was to compare torsional stability of the expandable intramedullary nail and locked standard nail (T2 femoral nail, Stryker, Mathwah, USA) in case of transverse (OTA 32-A3) fracture. Fixion nail was inserted without reaming. Statically locked nails were inserted after reaming of the medullary canal. Bone-nail systems were loaded with torsional moment between -1 Nm and 10 Nm around anatomical axis at 1 Hz for 5000 cycles.

14 of 20 samples fixed with expandable nail of first generation failed after the first loading cycle. Only one sample in each group of femurs passed 1000 loading cycles. All locked nails in healthy bones passed the test. Only three locked nails in osteoporotic group failed. 7 of 10 expandable nails of second generation failed after 100 loading cycles. No locked nails failed during 5000 loading cycles.

Table 3. Fixion vs locked nails stiffness and strength characteristics

№ in reference list	Bone	Fracture	Stiffness/Strength	Fixion nail	Locked nail
[3]	Humeri	Tranverse, 3 mm gap	Lateral bending stiffness, kN/mm, M±SD	0.73±0.14	0.61±0.1
			Frontal bending stiffness, kN/mm, M±SD	0.67±0.18	0.58±0.09
			Torsional stiffness, N*m/degree, M±SD	0.13±0.19	0.43±0.09
[2]	Tibia	Transverse	Bending stiffness, N/mm, M (min-max)	280.8 (224.7-336.8)	222.7 (169.5-275.9)
			Torsional strength, N*m, M (min-max)	12.6 (8.1-17.1)	26.1 (14.3-37.9)
			Torsional stiffness, N*m/degree, M (min-max)	2.80 (1.62-3.97)	2.72 (0.07-5.37)
[10]	Humeri	Spiral	Torsional stiffness without proximal lock, N*m/degree, M±SD	0.960±0.315	0.885±0.39
			Torsional stiffness with proximal lock, N*m/degree, M±SD	0.985±0.260	
	Tibia	Transverse	Torsional stiffness relatively intact bone, %, M±SD	10.0±7.5	20.5±5.0
[14]	Femur	Proximal fracture	Maximal hip peg pull-out force, N, M	268	298.8
			Maximal hip peg torsion moment, N*sm, M	128.9	25.6

Fixion vs locked nails stiffness and strength characteristics are shown as they were presented in reviewed papers. M, mean; SD, standard deviation; min – minimal value; max – maximal value.

Tibia and humeri

In [11] Maher and coauthors investigated torsional stability and stiffness of the bone-nail system for 6 pairs of tibial and humeral bones with diaphyseal fractures treated with either expandable (Fixion) or locked (Zimmer M/DN, Zimmer, Warsaw, Poland) nails. Each sample was loaded with torsional moment of +-5 N*m at 1 N*m/s speed for four preconditioning cycles and one loading cycle with the help of biaxial loading testing machine. The slope of torsional moment between -3.5 Nm and 3.5 Nm was used for the torsional stiffness evaluation. Mids-haft fracture was modelled for tibias and spiral fracture was created for humeral bones. Fixion nails were installed without reaming. According to the manufacturer's recommendations, 1 mm reaming was used for each Zimmer M/DN nail. If bone-nail system could not withstand five loading cycles, it was thought that the system had not passed the test.

During loading two Fixion constructs failed the test. Zimmer M/DN for tibia showed significantly higher stiffness than Fixion nail. Humeral spiral fracture models did not demonstrate significant differences in torsional stiffness between expandable and locked nails. Proximal interlock has no impact on the stiffness of the bone-Fixion nail system.

Stability of expandable Fixion and locked Grosse and Kempf (Stryker, USA) nails in case of tibial mid-shaft fractures was investigated in [9]. Locked nails were inserted with reaming procedure and expandable nails were installed without reaming. Mechanical testing of 8 pairs cadaver bones was performed for lateral (reaching 3 mm lateral deformation and removal of load) and torsional (20 N axial force and torsional moment of 1 Nm) loads. Such loads are 10% lower than failure load and so they do not cause serious damage to the bone structure. Torsional rigidity was evaluated at the slope between -1 N*m and 1 N*m. After torsional stiffness evaluation moment was applied until structure failed (20 degree rotation). During this procedure compressive axial load of 150 N was applied to the construct. Lateral stiffness for expandable nail (average value of 280.8 N/mm) was 25% higher than for locked nail (average value of 222.7 N/mm). Both nails showed similar average torsional stiffness. During torsional loading bone-locked nail system was broken at distal screw installation area, while system with expandable nail failed by slippage betwenn nail and bone fragments. Torsional strength for expandable nail (peak torque of 12.6 Nm at an angle of 20 degrees) was two times lower than for the locked nail (peak torque of 26.1 Nm at an angle of 20 degrees).

Objective of the work [10] was to compare bending and torsional stiffness of expandable and standard locked Synthes nails used for humeral bone. Authors investigated transverse fracture with 3 mm gap. Both systems (expandable Fixion and locked Synthes) showed similar values of bending stiffness (average lateral bending stiffness was 0.7±0.14 and 0.63±0.1 kN/mm, average frontal bending stiffness was 0.76±0.18 and 0.58±0.09 kN/mm for expandable and locked nails respectively). Torsional stiffness was 0.13±0.19 и 0.43±0.09 Nm/degree for expandable and locked nails respectively. Lower torsional stiffness for expandable nail was obtained for funnel shaped proximal intramedullary canal of the bone.

Discussion

Expandable nail Fixion is a relatively new development and is used in medical practice since 1999. Numerous clinical and retrospective works devoted to this nail are published. Most authors point out the advantages of the new nail compared to "standard" fixation system. Fixion nail does not require reaming procedure and distal locking screws installation, which significantly reduces surgical time and radiation exposure on surgeon and patient. In addition, it is very comfortable in use for young surgeons who do not have enough experience of intramedullary fixation.

It is important to note, that according to authors of clinical practice expandable nail provides sufficient stability of long bone fracture fixation. Despite the fact that reaming is not required, authors [4] believed that exactly reaming of medullary canal allowed them to obtain stable fixation of bone fragments and to avoid postoperative complications. In systematic reviews, authors also point out the advantages of the new nail compared to standard nails. However, authors conclude that expandable nail requires further study [2, 3].

It is surprising but biomechanics of expandable nail was studied quite poorly and only with the help of mechanical experiments on universal testing machines. All these works were published in a short period from 2005 to 2008. In recent years, such investigations were not executed or have not been published yet. It still seems strange because Fixion nail did not prove to be stable in most of the published studies. Thus, there are works devoted to the biomechanical comparison of the expandable and locked nails. However, these data are scattered and therefore are inconvenient for analysis.

The comparative strength and stiffness characteristics of expandable and locked nails are summarized in *Table* 3. Format of numerical data presentation in *Table* 3 corresponds to the data format of original reviewed articles.

Table 3 leads to the following conclusions. Firstly, expandable nail had shown high stiffness in case of lateral loads [9, 10]. In these both works, lateral stiffness was higher for systems with Fixion nail. In fact, the method of nail installation provides this feature.

However, in case of torsional loading expandable nail showed itself not in the best way. In three studies [9-11] torsional stiffness of bone-nail system was significantly lower (twice or more) than the stiffness for standard nail. At the same time, numerical values of torsional stiffness obtained in [10] and [11] were very similar. Moreover, five of eight samples in [10] allowed proximal fragment, fixed with Fixion nail, easily to rotate relative to the distal part before performing the experiments. In [11] authors noted that two of five Fixion-implanted tibial osteotomies exhibited similar failure. In [12], authors showed that in the case of mid-shaft fractures of healthy and osteoporotic bones expandable nail in almost all experiments did not provide sufficient torsional stability. Not more than 20% of all healthy bones passed tests under cyclic loading conditions in the case of expandable nail installation. The authors also noted that contact area (working length) between nail ribs and medullary canal was significantly higher for those samples that passed tests. Importantly, these results concerning Fixion nail stability in the case of transverse fractures were obtained for femoral, tibial and humeral bones. However, in case of oblique humeral fracture [10] expandable nail showed higher torsional stiffness than standard nail. Moreover, experiments have shown that proximal locking of the nail did not affect the rigidity of the system. Authors suggested that Fixion nail is not ideal for stabilization of mid-shaft osteotomies. This nail may be more suitable for such fracture types in which loads across the fracture could be shared between the nail and bone fragments.

Experiment [14] on the measurement of the hip peg torsion should be noted. Here, the proximal Fixion nail exceeded the standard nail 5 times in force value (128.9 N vs 25.6 N). Maximum hip peg pull-out force was comparable with this parameter of standard proximal locked nail. Fixion nail passed fatigue tests [14] according to ASTM F384 standard so it demonstrated its safety for long-term use.

Kummer [15] and Steinberg [14] argued that expansion of the nail does not create high internal pressure so the nail does not cause damage to the bone tissue. Moreover, they noted that due to the large bone-nail contact area pressure should be distributed uniformly.

Thus, despite the fact that the expandable nail shows promising results in clinical trials, there have been published a number of biomechanical studies in which Fixion showed "failing" [12] and not enough good results [9-11], when assessing the stability of transverse diaphyseal fractures of long bones. One can argue, as Steinberg [15] does in his comments on the article [16] that the nail was not installed correctly. However, Blum explained that installation was carried out in exactly to the manufacturer's recommendations. Other authors have also pointed out in their articles that the expandable nails were placed exactly to the requirements of the manufacturer. Thus, Blum and coauthors believed that Fixion nail showed the lower torsional stiffness in comparison with locked nails for the reason that they have studied bones, which had significant differences in the diameter of the medullary canal in proximal and distal parts. While the nail may work well in the case of young patients, it cannot show a sufficient stability in the case of elderly patients and osteoporotic bones. It should be understood that in addition to selecting a suitable nail, surgeon should install it correctly into the bone to ensure sufficient contact area between nail ribs and bone fragments.

It seems to us that now it is necessary to continue biomechanical investigations on Fixion nail with the help of universal testing machines and computer finite-element modeling techniques. It is important to identify all the disadvantages of the nail so that surgeons can consider them during surgical operations and minimize post-operative risks and complications.

Our future work will be focused on biomechanical modeling of femur bone osteosynthesis with Fixion nail loaded with cyclic loads, which take into account kinematics of the system, as well as loads that arise during walking.

Conclusions

For the main conclusion we can say the following. Fixion nail could be used with great caution for osteosynthesis of long bones mid-shaft fractures. In contrast, in the case of oblique and spiral fractures, when the contact area between the fragments is sufficiently high, and can transmit the load between the nail and bone fragments, the expanding nail should be used. Of particular note is the use of the nail in bone reconstructive surgery, which requires reaming of the medullar canal.

Conflict of interest

There is no any conflict of interest.

References

1. Beazley J, Mauffrey C, Seligson D. Treatment of acute tibial shaft fractures with an expandable nailing system: a systematic review of the literature. *Injury* 2011; 42 suppl 4: s11-s16. (PMID: 21939797) (doi: 10.1016/S0020-1383(11)70006-7)
2. Rose DM, Smith TO, Nielsen D, Hing CB. Expandable intramedullary nails in lower limb trauma: a systematic review of clinical and radiological outcomes. *Strategies Trauma Limb Reconstr* 2013, 8(1): 1-12. (doi:10.1007/s11751-013-0156-9) (PMID: 23475316)
3. Rose DM, Smith TO, Nielsen D, Hing CB. Expandable intramedullary nails for humeral fractures: a systematic review of clinical and radiological outcomes. *Eur J Orthop Surg Traumatol* 2013; 23(1): 1-11. (doi: 10.1007/s00590-011-0908-5) (PMID: 23412402)
4. Zhou ZT, Song YC, Zhou XZ, Zhou HB, Luo ZP, Dong QR. Femoral midshaft fractures: expandable versus locked nailing, *Orthopedics* 2015; 38(4): e314-e318. (doi: 10.3928/01477447-20150402-60) (PMID: 25901625)
5. Lepore S, Capuano N, Lepore L, Romano G. Preliminary clinical and radiographic results with the fixion intramedullary nail: an inflatable self-locking system for long bone fractures. *J Orthop Traumatol* 2000; 1(3): 135-140. (doi: 10.1007/s101950070005)
6. Bong MR, Kummer FJ, Koval KJ, Egol KA. Intramedullary nailing of the lower extremity: biomechanics and biology. *J Am Acad Orthop Surg* 2007; 15(2): 97-106. (PMID: 17277256)
7. Cheung G, Zalzal P, Bhandari M, Spelt JK, Papini M. Finite element analysis of a femoral retrograde intramedullary nail subject to gait loading. *Med Eng Phys* 2004; 26(2): 93-108. (PMID: 15036177) (doi: 10.1016/j.medengphy.2003.10.006)
8. Efstathopoulos N, Nikolaou VS, Xypnitos FN, Korres D, Lazarettos I, Panousis K, et al. Investigation on the distal screw of a trochanteric

intramedullary implant (fi-nail) using a simplified finite element model. *Injury* 2010; 41(3): 259-265. (doi: 10.1016/j.injury.2009.09.006) (PMID: 20176164)

9. Blomquist J, lundberg OJ, Gjerdet NR, Mølster A. Are inflatable nails an alternative to interlocked nails in tibial fractures? *Clin Orthop Relat Res* 2008; 466(5): 1225-1231. (doi: 10.1007/s11999-008-0169-8) (PMID: 18299950)
10. Blum J, Karagül G, Sternstein W, Rommens PM. Bending and torsional stiffness in cadaver humeri fixed with a self-locking expandable or interlocking nail system: a mechanical study. *J Orthop Trauma* 2005; 19(8): 535-542. (PMID: 16118561)
11. Maher SA, Meyers K, Borens O, Suk M, Grose A, Wright TM, Helfet D. Biomechanical evaluation of an expandable nail for the fixation of midshaft fractures. *J Trauma* 2007; 63(1): 103-107. (PMID: 17622876)
12. Oliveira ML, Lemon MA, Mears SC, Dinah AF, Waites MD, Knight TA, Belkoff SM. Biomechanical comparison of expandable and locked intramedullary femoral nails. *J Orthop Trauma* 2008; 22(7): 446-450. (doi: 10.1097/bot.0b013e318178d999) (PMID: 18670283)
13. Steinberg EL. Comment on bending and torsional stiffness in cadaver humeri fixed with a self-locking expandable or interlocking nail system: a mechanical study. *J Orthop Trauma* 2006; 20(4): 295; author reply 295-296. (PMID: 16721250)
14. Steinberg EL, Blumberg N, Dekel S. The fixion proximal femur nailing system: biomechanical properties of the nail and a cadaveric study. *J Biomech* 2005; 38(1): 63-68. (PMID: 15519340) (doi: 10.1016/j.jbiomech.2004.03.014)
15. Kummer FJ, Strauss EJ, Jaffe WL. Evaluation of an expandable stem total hip replacement system. *Bull Nyu Hosp Jt Dis* 2007; 65(2): 101-105. (PMID: 17581101)
16. Eveleigh RJ. A review of biomechanical studies of intramedullary nails. *Med Eng Phys* 1995; 17(5): 323-331. (doi: 10.1016/1350-4533(95)97311-C) (PMID: 7670691)

Authors:
Dmitry Ivanov – PhD, Deputy Head of Department, Educational-Research Institute of Nanostructures and Biosystems, Saratov State University n.a. N.G.Chernyshevsky, Saratov, Russia.
Anatoly Barabash – MD, DSc, Head of Department, Saratov Scientific Research Institute of Traumatology and Orthopedics, Saratov, Russia.
Yuri Barabash – MD, DSc, Professor, Saratov Scientific Research Institute of Traumatology and Orthopedics, Saratov, Russia.