Straight versus modular nail: Analysis of mechanical properties two knee arthrodesis methods.

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ABSTRACT

Background

Complications after arthroplasty often result in irreversible disability. In some cases for the extremity to be salvaged, the permanent knee joint arthrodesis is the last-chance procedure.

Modular implant design simplifies surgical technique but modularity may potentially compromise mechanical strength of an implant. Mechanical properties of the implant are particularly important in case of knee arthrodesis without bone-on-bone contact where forces during gait and weight bearing are transmitted directly through the nail.

The aim of this article was to perform comparative analysis of the mechanical properties of modular nail CHARFIX2 FN, when compared to the femoral nail, used for knee arthrodesis; and to analyze the effectiveness of treatment with use of this nail based on the observations of clinical cases.

Methods

Comparative analysis of: the static 4-point bending test, dynamic 4-point bending test and static torsion test. All tests were performed in accordance with requirements of ASTM F 1264. A clinical analysis of 5 cases, in which CHARFIX2 FN nails were used, was also performed.

Results

Based on the results of mechanical tests, the strength characteristics of CHARFIX2 FN nail have been found superior and more advantageous than corresponding features of the standard femoral nail. For CHARFIX2 FN nail, the median for flexural stiffness was almost 4 times higher and for maximum torque value was almost 2 times higher when compared to the femoral nail. Observations of the clinical cases
gave satisfactory results.

Conclusions

The obtained mechanical tests present significant differences between CHARFIX2 FN and the femoral nail in mechanical strength and, therefore, its improved stability and safety for patients during walking. It can be used for permanent knee immobilization with satisfactory clinical results. The functional outcomes and subjective measurements of pain in patients treated with CHARFIX2 FN group are satisfying.

Keywords: knee arthrodesis, biomechanical testing, modular nail

BACKGROUND

Total knee arthroplasty (TKA) is one of the most commonly performed in-patient surgical procedures worldwide. In the USA, about 600,000 knee arthroplasty procedures have been performed annually since 2010 [1]. In Poland, according to the National Central Arthroplasty Database, 27,653 TKAs were conducted in 2017, which accounts for over 32% of all joint replacements [2].

Complications after arthroplasty often result in irreversible disability. In some cases for the extremity to be salvaged, the permanent knee joint arthrodesis is the last-chance solution [3, 4, 5].

Currently, knee arthrodesis with a stainless steel or titanium intramedullary nail is the treatment of choice [6], in contrary to external fixators associated with higher complication rates [7]. As reported by Lee et. al., average loads yielded by titanium nails are significantly higher in comparison with stainless steel implants, despite higher linear stiffness of the latter [8].

Modular implant design simplifies surgical technique, limits intraoperative damage of the tissues and improves clinical results [9]. Moreover, the usage of dedicated spacers facilitates defects
reconstruction in cases with severe bone loss, reducing loads acting directly on the nail [10]. On the other hand, modularity may potentially compromise mechanical strength of an implant. To date, there are no studies directly comparing mechanical properties of modular and straight nails designed for knee arthrodesis. Mechanical properties of the implant are particularly important in the case of knee arthrodesis without bone-on-bone contact, where forces during gait and weight bearing are transmitted directly through the nail.

The aim of this study is to perform a comparative analysis of a new design modular nail dedicated for knee joint arthrodesis with standard, non-modular implant.

METHODS

Description of the modular implant

Fig. 1. Femur Nail, Right 8x480mm

Figure 1 presents a femoral nail (ChM Femur Nail, Right 8x480mm) made of Ti6Al4V that has been used during dynamic and static tests.
Fig. 2. CHARFIX2 FN nail

CHARFIX2 FN nail (Fig. 2) (ChM, Lewickie, Poland) is used to connect the femur and tibia at the place of the knee resection or when the joint surface has been partially removed. The complete implant consists of a femoral and tibial module, a distance (*optional*), screws T that join the modules and offered separately screws for locking the nail modules in medullary cavity. All the elements are made of Ti6Al4V. CHARFIX2 FN nail enables permanent stiffening of the knee joint, preserving its physiological curvature of about 7 degrees and with a bending angle not exceeding 5 degrees.

**Mechanical tests**

Femoral nails (ChM Femur Nail, Right 8x480mm; cat. no. 3.2852.480) and CHARFIX2 FN nail (cat. no. 3.6301.180, 3.6341.180, 3.6300.000 - femoral module, tibial module and screw T, respectively) were tested.

The static 4-point bending test, dynamic 4-point bending test and static torsion test were
performed. Six CHARFIX2 FN nails and six femoral nails were investigated in each test.

Mechanical tests on femoral nails were performed by Accutek Testing Laboratory, Ohio, in accordance with ASTM F 1264 [11]. The tests were performed using the MTS Test Machine.

In the static 4-point bending test, the distance between: the loading rollers was 76 mm, the support rollers was 228 mm and the diameter of the rollers was 25 mm.

In the dynamic 4-point bending test, the roller spacing and diameter were analogous to these used in the static test; the load factor was ≥10 and the frequency was 5 Hz. The assumed number of cycles was 1,000,000.

In the static torsion test, the measuring length was 230 mm.

CHARFIX2 FN nails were tested in the ChM measuring laboratory. The following equipment was used for testing: MTS Insight 100 testing machine, MTS Bionix.

In the static 4-point bending test, the distance between: the loading rollers was 100 mm, the support rollers was 230 mm and the diameter of the rollers was 25 mm. The test speed was 5 mm/min, the initial force was 10 N, and the data acquisition frequency was 100 Hz.

In the dynamic 4-point bending test, the roller spacing and diameter were analogous to these used in the static test. The stress ratio was R: 0.1 and the frequency was 5 Hz. The assumed number of cycles was 1,000,000.

In the static torsion test, the measuring length was 230 mm, with a test speed of 1 rpm (360°/min) and a data acquisition frequency of 100 Hz.
Fig. 3. Test setup for static and dynamic 4-point bending tests (CHARFIX2 FN, ChM Laboratory)

Figure 3 presents a setup of a tested implant for static and dynamic 4-point bending tests.
Fig. 4. Nail after static bending test (CHARFIX2 FN, ChM Laboratory).

Figure 4 presents the nail after static 4-point bending test.

**Statistical analysis**

The results of mechanical tests (static 4-point bending and static torsion test) were analyzed statistically. Six nails were tested in each group; therefore, the results received are characterized by high stability. Statistical analysis of data was performing by using Statistica for Windows. Normality was checked using the Shapiro-Wilk test. The non-parametric Mann-Whitney U test was chosen to compare the results in individual groups, verifying the existence of statistically significant differences between the medians.
Description of surgical treatment

Surgical treatment depends on the degree of knee joint damage. For failed arthroplasty with extensive bone losses, the use of cemented nail with distances (spacers) is recommended, so that the limb shortening does not exceed 1-1.5 cm (such shortening of the limb facilitates walking with a permanently stiffened knee joint).

In post-traumatic cases with only a small loss of articular surfaces, cementless nail implantation is suggested with locking the nail in the dynamic holes to enable direct transferring of loads through the bone surfaces, thus facilitating the bone union.

The use of a unique and strong hinge in the nail allows for easy and reliable connection of its modules and walking with full load the very next day after surgery.

Clinical evaluation

The follow-up schedule consisted of outpatient visits after 6 weeks, 6 months, and then once a year. During the last follow-up the functional outcome was measured according to Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and Oxford Knee Score, the severity of pain was assessed using the Visual Analog Scale (VAS). The gait was evaluated and shortening of the affected limb in relation to the other were measured.

RESULTS

Table 1 presents the results of static 4-point bending test for both implants. For CHARFIX2 FN nail, the median for flexural stiffness (324 N/mm) is almost 4 times higher when compared to the femoral nail (86 N/mm) (p < 0.05), the difference is statistically significant.
| Bending Stiffness [N/mm] | ChM Femur Nail | Nail CHARFIX2 FN |
|--------------------------|---------------|-----------------|
| 1                        | 87            | 322             |
| 2                        | 87            | 324             |
| 3                        | 89            | 329             |
| 4                        | 84            | 320             |
| 5                        | 83            | 324             |
| 6                        | 80            | 323             |
| **Average**              | **85**        | **324**         |
| **Std Dev**              | **3**         | **3**           |
| **Median**               | **86**        | **324**         |
| **First quartile**       | **83**        | **322**         |
| **Third quartile**       | **87**        | **324**         |
Fig. 5. Graphic representation of results comparing flexural stiffness in both groups of nails

Table 2. Results of dynamic 4 point bending

|   | Load [N] | Bending Moment [Nm] | Number of Cycles |
|---|----------|---------------------|------------------|
| ChM Femur Nail | 1 | 700 | 27 | 1000000 |
|   | 2 | 700 | 27 | 1000000 |
|   | 3 | 830 | 32 | 1000000 |
|   | 4 | **830** | **32** | **95412** |
|   | 5 | 900 | 34 | 74980 |
| Nail CHARFIX2 FN | Load [N] | Bending Moment [Nm] | Number of Cycles |
|-----------------|----------|---------------------|-----------------|
| 6               | 960      | 36                  | 160400          |
| 1               | 1200     | 78,0                | 1000000         |
| 2               | 1400     | 91,0                | 1000000         |
| 3               | 1500     | 97,5                | 1000000         |
| 4               | 1500     | 97,5                | 1000000         |
| 5               | 1600     | 104,0               | 60000           |
| 6               | 1940     | 126,1               | 20300           |
The results of the static torsion test presented in Table 3 proved that the median for maximum torque value obtained for CHARFIX2 FN nails was 76.1 Nm; whereas for femoral nails group - 43.6 Nm (p < 0.05), the difference is statistically significant.

Table 3. Results of static torsion

| Static Torsion       |
|----------------------|
| ChM Femur Nail       |
| CHARFIX2 FN Nail     |
### Static Torsion

| Ultimate Torque [Nm] | ChM Femur Nail | Nail CHARFIX2 FN |
|----------------------|----------------|------------------|
| 1                    | 40.7           | 76.6             |
| 2                    | 49.5           | 76.6             |
| 3                    | 43.1           | 76.6             |
| 4                    | 44.0           | 75.5             |
| 5                    | 44.6           | 71.3             |
| 6                    | 41.5           | 74.8             |
| **Average**          | **43.9**       | **75.2**         |
| **Std Dev**          | 3.1            | 2.1              |
| **Median**           | **43.6**       | **76.1**         |
| **First quartile**   | 41.5           | 74.8             |
| **Third quartile**   | 44.6           | 76.6             |

Fig. 7. Graphical representation of results comparing the maximum torsional moment in both groups of nails.
In Orthopedic Department of Centre of Postgraduate Medical Education (CPME) in Otwock, Poland, five knee arthrodesis procedures were performed secondary to the complications after knee arthroplasty. A cemented version of CHARFIX2 FN nail was used for each patient, obtaining in all cases a satisfactory result within 2-3 years follow-up.

In the years 2017-2019, 5 patients were subjected to knee arthrodesis with use of CHARFIX2 FN nail at Orthopedic Clinic CPME in Otwock. In each case, recurrent periprosthetic joint infection with concomitant failure of the extensor mechanism was the reason for qualifying the patient for arthrodesis procedure. The group included 4 women and a man at an average of 71.6 (53.9 - 79.7) years. All nails were cemented. Due to extensive bone loss, a spacer was used in each patient. The mean follow-up was 2.2 (2 - 2.85) years. No recurrence of infection was observed. During outpatient control, the severity of pain using the Visual Analog Scale (VAS), physical function using Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and Oxford Knee Score, gait independence and shortening of the affected limb in relation to the other were measured [12].

The mean VAS pain score was 2.2 (0 - 6) of which 2 patients felt no pain at all. The average functional score on the WOMAC scale was 45 (32 - 60) and for Oxford Knee Score – 32.6 (27 – 39).

Each patient after the rehabilitation process achieved an independent painless gait. Three
patients reported the use of crutches outside home. The average limb shortening was 2.6 cm (1.6-3.5). The patient with the smallest shortening (1.6 cm) reported periodic tripping over her foot tip during walking. However, 1 cm shoe insert for the other side solved the problem. Two patients had been complaining about foot pain at the treated side for several months after surgery, which eventually resolved over time.

Each of the 5 patients treated positively evaluated the procedure results and, if necessary, would again decide on this form of treatment.

During follow-up, no complications or problems with implants were observed.

DISCUSSION

In comparison with standard femoral nail, CHARFIX2 FN offers superior flexural stiffness and fatigue strength assessed with static and dynamic 4-point bending tests, respectively. Moreover, results obtained with the static torsion test showed that for CHARFIX2 FN nail, the average value of the maximum torsional moment at which the plastic deformation of the device occurred was twice as high as for the femoral nail. Due to the cyclical, long-lasting loads, the use of an implant with greater fatigue strength is crucial for successful knee arthrodesis, reducing the risk of implant damage and, finally, the need for revision surgery. Literature review proves such comparison to be the first published.

Metal implants respond differently to dynamic overload than bone tissue, which is a composite structure; therefore, designing not only implant response to acting forces, but also interaction between the device and tissues, must be considered [13,14]. Results reported by Yang et al. [15] revealed superiority of intercalary spacer (segmental defect replacement prosthesis; Osteobridge IDSF over intramedullary nail combined with PMMA cement in terms of bone-to-implant interface stability in 10 matched pairs of humeral specimens with segmental bone defects. The OsteoBridge IDSF demonstrated a significantly greater stability in torsion, compression, and in all modes of 4-point bending test. Similar results were published by Henry et al., who compared peak torque and stiffness between second generation titanium modular intercalary humeral spacer with those of a modern locked humeral nail combined with methylmethacrylate or with an intercalary allograft spacer (allograft nail composite) for fixation of
segmental defects of the humeral diaphysis [16]. In the study, reconstruction with a cemented metallic intercalary spacer provided significantly greater immediate stability than intramedullary nail fixation supplemented with segmental methylmethacrylate or intercalary allograft reconstruction.

The commonly used long femoral nails like ChM Femur Nail have some limitations. They require an additional surgical approach in the trochanteric region. Their construction and geometry prevent full control of the tibia/femoral positioning, making the corrections of valgus, flexion and rotation impossible. With use of long femoral nails, it is not possible to reconstruct or partially correct the length of the limb; it is not also possible to use the nail in more complex deformations of the femur or tibia [6]. Complications related to the use of the intramedullary nail fusion technique include nail migration, delayed or nonunion, nail breakage, and distal tibial fractures which can occur in up to 40 - 50 % of cases [17].

The ideal method of arthrodesis should have the lowest possible risk of complications, lack of nuisance associated with the implant, and limitation in possible need for further hospitalization or surgical treatment. A modular nail like Charfix2 FN requires one surgical approach, usually in an old scar. It can be implanted in the presence of hip endoprosthesis and its modularity with surgical technique allows for its use in femoral or tibial bone deformations. The healing effect is achieved directly after the operation, because using the method without bone-on-bone contact does not require waiting for the arthrodesis fusion. Another advantage is its easy removal and exchangeability in case of recurrence of infection. The use of spacers reduces the risk of implant migration and enables reconstruction of the desired length of the limb, which in the case of an extensive loss of bone tissue — with the need to obtain contact of bone fragments — reduces the risk of damage of vascular structures [6].

In our study group, the mean VAS pain score was 2.2 (0 - 6) and the average functional score on the WOMAC scale was 45 (range 32 - 60), a moderately poor functional result [18]. The Oxford Knee Score – 32.6 (range 27 – 39) is also moderately poor functional result [19]. In recent papers, reported clinical outcomes after knee arthrodesis with modular and straight nails VAS score range 2.9-3, Oxford Knee Score range 38-39.2 and WOMAC score was 55.8[20-22]. The functional outcomes and subjective measurements of pain in our patient group are comparable to these results. The reason for the poor functional results was the fact that the knee has been stiffened, which eliminated pain but significantly
limited daily activity of patients. Knee arthrodesis is a salvage procedure that saves the lower extremity from amputation.

Leg shortening is functional, but also psychological issue which is often observed in patients after knee arthrodesis. Wood et. al. presented that limb shortening after knee arthrodesis can reach up to 5 cm [23]. In our group, the average shortening was 2.6 cm, with positive levels of patients acceptance. The literature describes individual cases of knee joint arthrodesis with use of intramedullary stabilization and supplementation of bone loss with a spacer that would transfer the loads directly from the femur to the tibia, enabling equalization of the length of the limbs and protecting the nail against overloading at the bone loss site [24].

Proposed ideal frontal lower limb alignment was 5° to 7° valgus [16]. Conway et al. showed that stiffening of the knee with femoral nail often leads to 2°-5° varus limb alignment [25]. Thanks to modular design of CHARFIX2 FN, the optimal alignment has been estimated at 5°-7° valgus.

Patients with hip endoprosthesis comprise a group in which technical problems occur when knee arthrodesis is necessary. The femoral nail is contraindicated in this specific group. The method of choice in these patients is modular nail. An important aspect that should be taken into consideration is a gap between the nail and stem of the hip endoprosthesis. Excessively small gaps pose a risk of femur fracture and development of minor resistant point in femur bone. Optimal gap should be at least 10 cm [26].

There are several limitations in this study. Results obtained in mechanical in - vitro studies do not replace in - vivo testing. Another limitation is the relatively short follow-up in clinical observation and small cohort of patients. Therefore, the prospective well-planned studies will validate our findings in complication rate and survival curve of the implant.

CONCLUSIONS

Analyzing the results of the performed tests, CHARFIX2 FN nail can be concluded to have a much greater mechanical strength when compared to the femoral nail and therefore, provides improved stability and safety for the patient during walking. With similar clinical purpose of both nails, implantation using a single surgical approach and the possibility of using the nail for patients with implanted hip prosthesis are unquestionable additional advantages of CHARFIX2 FN nail.
LIST OF ABBREVIATIONS

TKA: Total Knee Arthroplasty

WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index

OKS: Oxford Knee Score

VAS: Visual Analog Scale

PMMA: Poly(methyl methacrylate)

DECLARATIONS

Ethics approval and consent to participate

This research project was approved by the ethics committee of our institution. All patients provided informed consent for participation.

Consent for publication

Not applicable

Availability of data and materials

The datasets analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

A. Sobolewski is an employee of ChM sp. z.o.o and at the time this research was conducted has received remuneration and other compensation.

All other authors declare that they have no connections or financial dependence on any organization, or anyone with a direct financial contribution to the subject of research, or materials studied in this work, e.g. through employment, consulting, ownership of shares or fees, except for those listed in the attachment or editorial letter.
Funding

The authors received no specific funding for this work.

Authors' contributions

Jerzy Białecki, Marcin Para, Andrzej Sobolewski conceived and designed the study, analyzed and interpreted the results, drafted the manuscript and revised it critically. Maciej Kogut and Paweł Bartosz, analyzed and interpreted the data, and revised the manuscript critically for intellectual content. All the authors have read and approved the submitted manuscript.

Acknowledgements

The authors acknowledge ChM for providing the results of tests presenting the strength characteristics of femoral and CHARFIX2 FN nails.

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