PRIMARY STABILIZATION OF HUMERAL SHAFT FRACTURES: AN EXPERIMENTAL STUDY OF DIFFERENT OSTEOSYNTHESIS METHODS

VILSON ULIAN[1], NILTON MAZZER[2], CLÁUDIO HENRIQUE BARBIERI[3], CARLOS ALBERTO MORO[4], LUIZ ANTONIO ALCÂNTARA DE OLIVEIRA[5]

SUMMARY

Objective: The purpose of this study was to assess primary stabilization of humeral shaft fractures using three different methods of fixation, represented by a DCP type plate, applied as a bridge plate, an uncommon synthesis material named SPS®, not previously described in literature and also used as a bridge plate, and a third type of material constituted by an intramedullary nail, with an uncommon locking provided by a distal cortical screw and a proximal Ender-type wire. Material and Method: Twenty-one pairs of human humeri were divided into three groups, each using one type of material for fixation, the bones of which were osteotomized, stabilized and submitted to nondestructive flexion-compression and torsion assays up to 200 N and 100 N respectively, and, in a crossing mechanism, the groups were again submitted to other torsion and flexion-compression assays, supported by statistical analysis. Results: The bridge-DCP group showed good resistance to the applied forces, similarly to the SPS® group, which, although presenting greater deflection, showed great elastic capacity. The intramedullary nail group showed good results in the flexion-compression assay due to the tutor mechanism of the intramedullary nails, but did not show resistance to the torsion forces.

Keywords: *Internal fracture fixation; Humeral fractures; Bone plates; Biomechanics.*

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INTRODUCTION

Surgical treatments have been notably evolving since 1917, when Hoglund(1) described a method for autogenous bone transplantation providing intramedullary fixation in a femoral fracture by using a bone graft removed from his own femur. Hey Groves, in 1919, reported the use of an axial tube for intramedullary fixation of a subtrochanteric femoral fracture. Küntscher(2), during the World War II, used intramedullary nails for fixation femoral shaft fractures. Hackethal(3) developed a technique for intramedullary fixation of the humerus with multiple wires. However, due to the poor performance of intramedullary nails, which did not provide rotational stabilization, Müller(4) developed a different internal fixation technique using plates and screws aiming to provide fixation stiffness and compression at the fracture core. The search for an optimal fixation method still remains, both for lower and upper limbs' bones.

Both the intramedullary fixation with nails and osteosynthesis with plates evolved its designs and assemblies, giving rise to blocked nails, as described by many authors(5,6) proximally and distally blocked nails, and plates(7,8) changing the concepts of rigid fixation into "biological" fixation, giving priority to alignment without absolute stability and promoting union by stimulating bone callus formation, trying also to minimize injuries on soft parts(9).

Based on this new concept of biological fixation, this study was aimed to test the relative stability of three different kinds of osteosyntheses in unstable humeral shaft fractures by means of mechanical flexion-compression and torsion assays.

MATERIAL AND METHOD

Twenty-one pairs of human humeri were used, which were removed from fresh cadavers, and following proper bioethics rules, obligatorily and primarily requiring a Free and Informed Consent Term for donation signed by family members or tutors, and complying with the rules set forth by CEMEL – Forensic Medicine Center, FMRP-USP for collecting human material, with the direct collaboration of the department of corneal donations collection of FMRP's Eye Bank. The 21 pairs of humeri were randomly distributed among three experimental groups, numbered according to the natural collection order, as follows: Group I, pairs nr. 3, 4, 5, 12, 18, 20 and 21; Group II, pairs nr. 2, 6, 8, 11, 13, 14 and 19; Group III, pairs nr. 1, 7, 9, 10, 15,

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Study conducted at the Bioengineering Laboratory, Department of Biomechanics, Medicine and Locomotive Apparatus Rehabilitation, Ribeirão Preto Medical School, University of São Paulo - FMRP-USP

Correspondences to: Rua A, Quadra I, Lote 02, Condomínio Parque Costa Verde - Piatã - Salvador, Bahia - Brasil - CEP 41650-120 - E-mail: vilsonulian@terra.com.br

1. Ph.D. in Medical Sciences, Focus on Orthopaedics and Traumatology, Ribeirão Preto Medical School, University of São Paulo - FMRP-USP, and Associate Professor of Orthopaedics and Traumatology, Department of Surgery, Medical School, Federal University of Bahia .
2. Associate Professor – Full Professor, Department of Biomechanics, Medicine and Locomotive Apparatus Rehabilitation, Ribeirão Preto Medical School, University of São Paulo - FMRP-USP
3. Chairman, Department of Biomechanics, Medicine and Locomotive Apparatus Rehabilitation, Ribeirão Preto Medical School, University of São Paulo - FMRP-USP
4. Engineer, Bioengineering Laboratory, Biomechanics, Medicine and Locomotive Apparatus Rehabilitation, Ribeirão Preto Medical School, University of São Paulo - FMRP-USP
5. Guest Professor, Ph.D., Department of Health, Feira de Santana State University – UEFS, Bahia.

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16 and 17. All the specimens were submitted to previous X-ray study in order to detect the presence of any gross changes that could cause bias to the results.

Specimens were prepared at the Bioengineering laboratory at FMRP-USP, after unfreezing to room temperature. In group I, a DCP plate was used as a bridge plate; in group II, the Pengo Synthesis System - SPS® was used, and; in group III, a blocked intramedullary nail was employed. Each bone was osteotomized at the mid third at a distance of 10 – 12 cm from the proximal edge of the olecranial pit, at a right angle to the long axis of the bone, with the resection of an 8-mm segment in the groups with DCP bridge plate and with the SPS® System, intending to cause a failure with the maximum instability. In the intramedullary nail group, no segment resection was made. All groups were submitted to flexion-compression and torsion tests with maximum load of 200N and 100N, respectively.

In group I, the use of 12-hole plates was standardized, being fixed with three consecutive screws (six cortical) on each end, keeping the 8-mm segmental failure. (Figure 1).

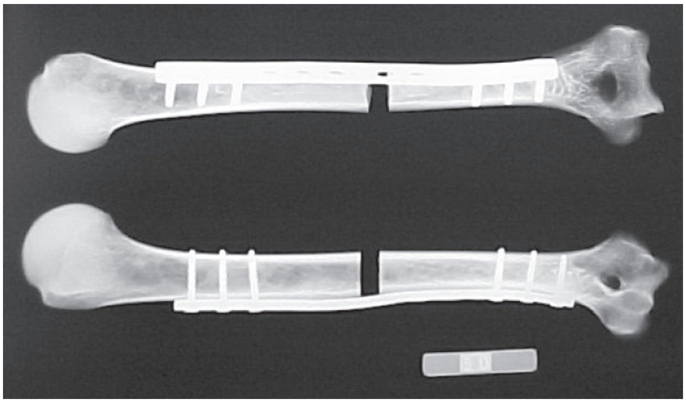


Figure 1 – *X-ray image of the DCP bridge plate assembly*

In group II, the use of two 3-hole plates was standardized for proximal and distal fixation as an assembly on a U-shaped nail of variable length according to the length of the specimens, keeping the 8-mm segmental failure (Figures 2, 3A and 3B).

In group III, the use of 7-mm intramedullary nail was standardized with retrograde access at 1 cm above the edge of olecranial pit, proximally blocked with Ender-type wire, also with retrograde insertion, impacting on the spongy bone at the humeral read region, and; distally, with bicortical fixation screw (Figure 4).

After fixation, all specimens were submitted to X-ray imaging tests in order to detect potential failures and to visualize where the implants were positioned.

The seven pairs of humeri in each group were further divided into two other groups, using simple randomization techniques such as 'heads or tails', thus obtaining two new groups containing seven humeri, which were submitted to flexion-compression or torsion assays called primary experimentation. By means of a crossing mechanism, the experiments were inverted in a second phase, and then called secondary experimentation. The crossing mechanism consists of using two kinds of test in a single specimen targeting the increase of the number of tests conducted in the study, thus increasing the "n" of the experiment, since these experiments are of a non-destructive type, with the secondary experiment being validated by means of statistical analysis (Kruskal-Wallis). For flexion-compression assays, a maximum load of 200N and a deflexion limit of 5 mm were adopted. For torsion assays, a maximum load of 100N, 2-Nm torque and deflexion limit of 30º were adopted.

For conducting assays, the models were fixed by their ends, including them with polymethylmetacrylate (PMMA), enabling the application of an anteromedial eccentric force at 3 cm from the flexion-compression axis center, and application of 2-Nm rotational force in torsion assays (Figure 5).

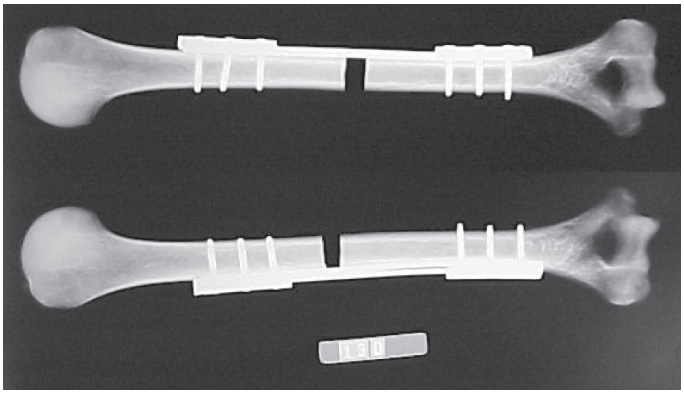


Figure 2 – *X-ray image of the SPS® assembly.*

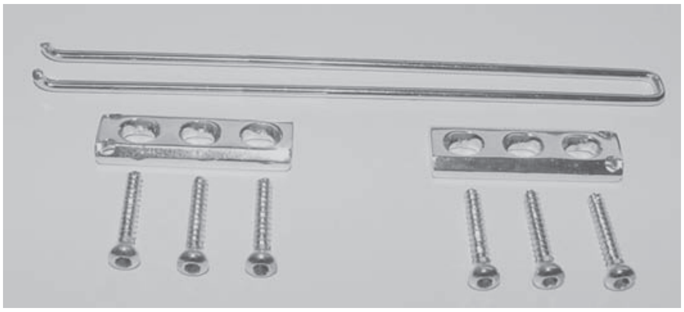


Figure 3A – *Osteosynthesis material SPS®.*

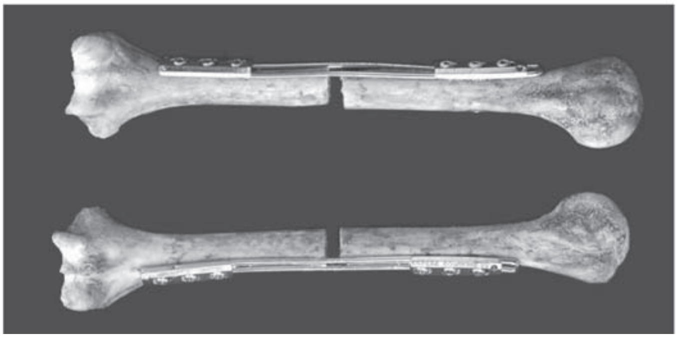


Figure 3B – *Osteosynthesis material SPS®, applied to the specimen.*

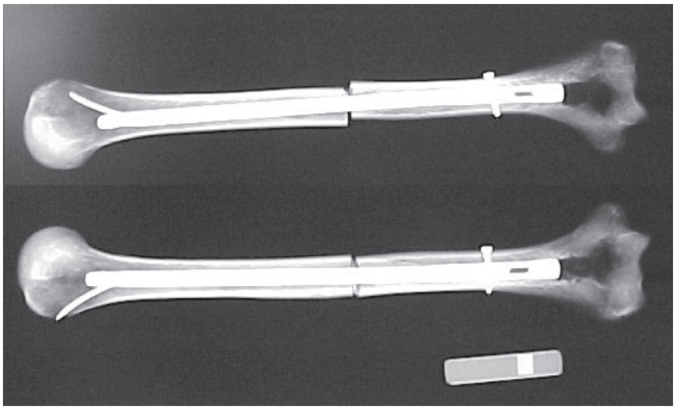


Figure 4 – *X-ray image of the intramedullary nail assembly.*

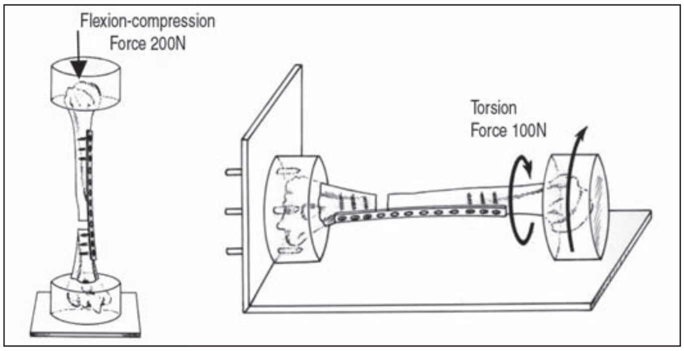


Figure 5 – *Mechanical flexion-compression and torsion assays.*

The evaluation of average values for Force and Deflexion among the three groups was made by means of the Kruskal-Wallis' test. The tests were carried out with the aid of the SPSS® (Statistical Package for Social Sciences) software version 10.0, being regarded as statistically significant any two-tail p values below 5% ($p<0.05$).

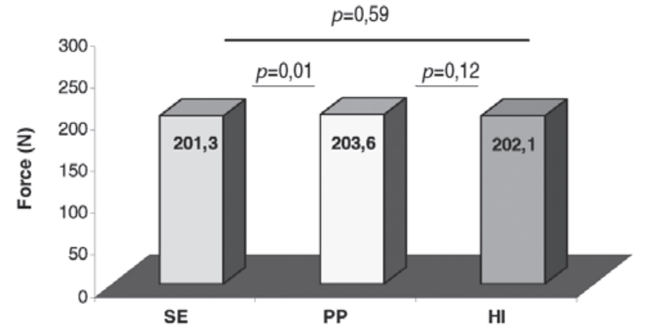
RESULTS

In biomechanical flexion-compression assays where the assemblies were submitted to forces of up to 200Nm the DCP bridge plate group showed deflexions ranging from 0.15588 mm to 0.4457 mm on primary experiment, and from 0.21914 mm to 0.34688 mm on secondary experiment. The SPS® group showed deflexions ranging from 0.45813 mm to 1.8082 mm on primary experiment, and from 0.27032 mm to 0.56801 mm on secondary experiment. The intramedullary nail group showed deflexions ranging from 0.29708 mm to 0.56283 mm on primary experiment, and from 0.24538 mm to 0.66605 mm on secondary experiment.

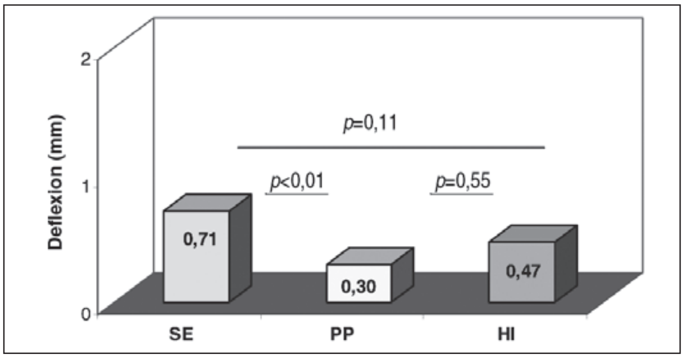
In biomechanical torsion assays where the assemblies were submitted to forces of up to 100N and 2-Nm torque, the DCP bridge plate showed deflexions ranging from 7.1904 mm to 8.5592 mm on primary experiment, and from 4.9192 mm to 8.2074 mm on secondary experiment. The SPS® group showed deflexions ranging from 13.298 mm to 26.206 mm on primary experiment, and from 22.035 mm to 26.280 mm on secondary experiment. The intramedullary nail group showed deflexions ranging from 9.6932 mm to 26.187 mm on primary experiment, and from 26.104 mm to 26.215 mm on secondary experiment.

Statistical Analysis

Concerning flexion-compression experiments, these were carried out with an eccentric load on the longitudinal axis of the specimens and limited to about 200N. The deflexion presented by the three groups showed differentiated capacities and characteristics of endurance, where the highest stability level was achieved by the group with DCP bridge plate ($p= 0.30$) (Table 1). Due to the technical challenges in keeping a segmental bone failure in the intramedullary nail group, only osteotomy was provided, keeping the contact between bone fragments' ends. This allowed for a better assembly resistance, causing the group to show a good resistance to loads on flexion-compression assays, as well as less deformity, with superior resistance to the SPS® or ES (elastic synthesis) assemblies (Graphs 1 and 2).



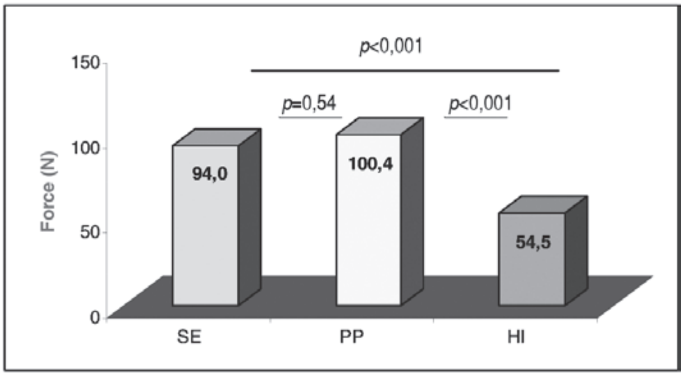
Graph 1 – *Result of the force applied on each group at flexion-compression test*



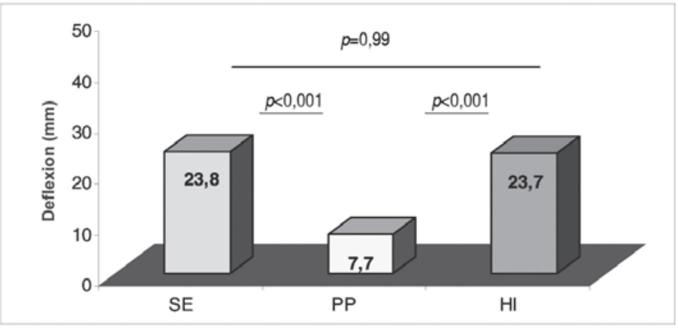
Graph 2 – *Result of the deflexion on each group at flexion-compression tests*

Concerning torsion experiments with load, these showed that the load values achieved were not statistically significant between DCP bridge plate and SPS® (ES) groups (p range = 0.54), but these were superior to the values achieved by the intramedullary nail group ($p = 0.001$) (Graph 3; Table 1).

The values achieved for deflexions were statistically significant among the DCP bridge plate and SPS® (ES) and intramedullary nail groups ($p= 0.99$) (Graph 4).



Graph 3 – *Result of the force applied on each group at Torsion tests.*



Graph 4 - *Result of the deflexion on each group at Torsion tests.*

Procedure		**Group**		***p***
Flexion-compression	**ES (n= 14)**	**BP (n= 13)**	**IN (n= 13)**	
Force	201.3 ± 1.3 (200.8)	203.6 ± 2.4 (203.6)	202.1 ± 2.0 (201.5)	**0.03**
Deflexion	0.71± 0.48 (0.51)	0.30 ± 0.07 (0.29)	0.47 ± 0.14 (0.47)	**0.005**
Torsion	**ES (n= 14)**	**BP (n= 13)**	**IN (n= 13)**	
Force	94.0 ± 9.0 (99.2)	100.4 ± 0.2 (100.4)	54.5 ± 26.4 (48.1)	**0.001**
Deflexion	23.8 ± 3.6 (25.3)	7.7 ± 1.0 (7.9)	23.7 ± 5.2 (26.1)	**0.001**

Values expressed as average ± sd and (median).

Table 1. *Force and Deflexion measurements on the three study groups according to the kind of procedure.*

DISCUSSION

Internal fixations have evolved from mechanical to biological properties. A flexible fixation must stimulate bone callus formation(10) while an indirect and less accurate reduction of the fracture may reduce surgical trauma, being this method described as “biological internal fixation”(11). A precise reconstruction and an absolute stabilization of the fixation, which, in the past, were considered as essential factors for a successful treatment(12,13) are evolving to new concepts of stabilization with minimal biological damages(9,14), with indirect and less precise reductions(8,15), and with the development of implants that reduce the contact with bone, such as the bridge plate(16,17), internal fixators(18) and technical novelties such as screw-blocking nuts(19). In the present study, three fixation techniques were used which are regarded as biological, intending to cause as minimum soft tissues detachment as possible.

The observation of experimental studies showed a wide range of load values applied on mechanical assays, most times of a destructive type and aimed to determine maximum values. In this study, a non-destructive mechanical assay was conceived using values proven to be above the required for providing basic movements of the humeral segment.

The loads employed were based on studied by Poppen and Walker(20). The approximate values of flexion-compression forces applied on the humerus at the osteotomy site in a 1.70m-high individual weighting 80 kg is about 52N; however, as a safety measure, loads up to 200N were used in this assay. Similarly, in torsion assays, loads of up to 100N were used, which are superior to the loads submitted on the humeral segment in upper limb’s rotation movements, estimated to about 20N, when using a 10-Nm torque, measured with a segment lengths table expressed as percentage, as developed by Drillis and Contini, according to the report by Winter(21).

Of the three groups with 7 pairs of humeri build for this experimental study, two were build according to two different assemblies with uncommon implant materials, represented by an intramedullary nail, and by a bridge plate known as SPS®; and the other group was represented by a DCP plate employed in clinical practice.

The seven pairs of humeri in the first group were fixated with DCP plates used as bridges, for this material has already been used in long bones’ fractures treatment, including humerus(22), and for still presenting limited experimental evaluation(23,24).

In the second group, the seven pairs of humeri were fixated with a material known as SPS®, employed in a similar way as the bridge plate technique developed according to novel trends in biological fixation, following those introduced by Ring and Jupiter(25), and Rozbruck et al.(14). This system recommends the use of a U-shaped nail on which a plate is attached to each end, providing minimal contact of the synthesis material with bone surface, as recommended by Leunig et al.(15). This system also enables the plate to be slid over the U-shaped nail, as well as the attachment of new plate segments for fixating intermediate fragments in the osteosynthesis of comminutive fractures (Figures 2, 3A and 3B).

The third group was built with seven pairs of humeri fixated with an intramedullary implant material using an uncommon method of nail blockage – a retrograde insertion – where distal locking was performed with the aid of a screw and the proximal locking with an Ender-type wire.

When assessed alone, we found that each of the specimens in the three groups showed a homogeneous behavior. When assessing flexion-compression assays among groups, a higher level of stiffness was seen for DCP bridge plate assembly was evident. DCP plates applied at dynamic compression and even at neutral compression lend good stiffness to systems, a fact that was also noticed on Group I in which the plate was used as a bridge (Graph 2), although a greater stiffness does not necessarily result in a higher bone union rate, as shown by Rubel et al.(24) in comparative studies with one and two plates.

The group with intramedullary nails showed a homogeneous behavior and good resistance during flexion-compression assays. The mechanism of action as tutor provided by the intramedullary nail justifies the behavior in this group, because although this was not a milled nail, it fills a large portion of the medullary channel, allowing for good support. These results are similar to the findings described by literature providing good resistance to flexion and compression forces shown by intramedullary nails(26,27). Maintaining the contact of osteotomy ends in this group has also contributed to its good performance in that assay.

At the flexion-compression assay, we found that the SPS®

group showed higher assembly elasticity due to its architecture, since, after applied load forces were finished, the assembly visually returned to its original position. This fact has not occurred with the intramedullary nails that do not have such elastic ability. We found that, despite of the statistic relevance found for deflexion variable in SPS® group, this does not translate into clinical relevance.

Torsion assays evidenced stiffness of the DCP bridge plate assembly and showed also some elasticity characteristics of the SPS® plate, in which the deflexion at load tends to go back to its original position when finished (Graph 4). Stiffness showed by intramedullary nails when submitted to torsion forces are directly related to its locking or blocking methods. Experimental studies[26,28] such the present one, have been conducted in order to address stabilization provided by different methods of nail blocking, intending to improve them.

This experimental study showed that the intramedullary nails group evidenced how challenging this kind of implant is to support rotation loads. This is also seen in literature, where reviews show that even the best blocking methods for intramedullary nails such as those provided by Russell-Taylor, UHN[29,30] and Polarus[27] nails still have a difficult blockage upon rotational forces. They also present technical limitations and surgical threats when providing proximal blockage.

In the intramedullary nail group, blockage is provided distally by a screw and proximally by an Ender-type wire; however, this hasn't shown to be able to support rotational loads. The technique recommends that the Ender-type wire is directed so as to occupy the trochiter or humeral head region, but no evidence was found that the spongy bone on these regions could have enough resistance to support the forces transferred to the Ender-type wire when applying rotational loads. A higher fixation capacity would be achieved if the wire could be fixated onto the cortical bone. This is not possible at the humeral head or trochiter region, because this would lead to damages on joint cartilage or on rotator cuff.

Nail design modifications are suggested, dislocating the Ender wire outlet to a further distal position to the nail's proximal end that could correspond to the humeral neck region, allowing for transfixing this region's cortical by the wire and thus providing a better locking condition.

The SPS® experimental group showed uncommon elastic characteristics never previously described in literature. It still presents a smaller amount of metal material to be implanted, as well as limited bone contact surface allowing for less soft tissues manipulation, with no damages to resistance when compared to the DCP bridge plate.

Modern trends toward "biological fixation" are well established with the use of bridge plates, both with DCP and SPS® plates, where the approach by two minimally invasive surgical accesses, result in less injury to soft tissues and less vascular damages to soft parts and bones.

CONCLUSIONS

1. DCP bridge plates show good resistance to loads in flexion-compression and torsion assays, evidencing a higher stabilization degree.
2. The Pengo Synthesis System (SPS®) showed good resistance in mechanical flexion-compression and torsion assays, demonstrating a transitory deflexion, going back to its original position after loads are released, thus showing its elastic ability.
3. The Pengo Synthesis System evidenced good stabilization of the assembly with values close to those of the DCP bridge plate group, proving to be applicable for use in the humerus. Its use in bones with load still requires experimental validation.
4. Intramedullary nails showed resistance to flexion-compression loads only in experiments with successful osteotomies due to the continuous contact between ends and to the tutor mechanism provided by medullary channel filling, but they did not present resistance to the torsion loads applied.

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