

Compression-locked nailing of the humerus

A mechanical analysis

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Background In the treatment of humeral fractures, reamed nailing and compression have been reported to give higher stability. In this cadaver study, we compared the Unreamed Humeral Nail (UHN) with the (reamed) Telescopic Locking Nail (TLN) to find out whether any differences exist concerning bending and rotational stability, both with and without compression.

Method Nails were tested in a paired set-up with 8 pairs of fresh frozen cadaveric humeri. The nail-bone constructs were submitted to axial distraction to test compression, four-point bending and torsion. After creating a bone defect simulating an unstable fracture, bending and torsional tests were run again

Results After cyclic loading, distraction under compression with the TLN was significantly less than with the UHN: 0.10 (SD 0.06) vs. 0.31 (SD 0.18) mm (difference = -67%, 95% CI = -84% to -37%; $p = 0.01$). In bending, the constructs with TLN under compression were stiffer than those with the UHN: 0.96 (SD 0.25) vs. 0.80 (SD 0.25) kN/mm (difference = 0.16, 95% CI = 0.07 to 0.25; $p = 0.01$). In torsion and with a bone defect, no significant differences were found.

Interpretation Both nails are capable of resisting physiological forces acting on the humerus. The constructs with the TLN under compression are more stable in bending. Compression with an axial set screw is the more stable option.

Due to distracting and rotational forces combined with a smaller bone contact area, transverse and short oblique humeral fractures are susceptible to delayed union and nonunion (Fattah et al. 1982, Dalton et al. 1993, Schatzker 1996, Jupiter and von Deck 1998, Blum et al. 1999, 2000, Blum and Rommens 2000). Torsional forces especially are thought to cause nonunion of humeral fractures treated with a locking nail (Schopfer et al. 1994, Zimmerman et al. 1994, Blum et al. 1999, 2000, Dujardin et al. 2000). According to the work of Ritter et al. (1987, 1991) and of Mittelmeier et al. (1989, 1990) on tibial and femoral nails, rotational forces in transverse fractures can only be excluded through interfragmentary compression. In a biomechanical study, Blum et al. (2000) found a higher bending and torsional stiffness for the Unreamed Humeral Nail under compression than for the same nail without compression.

The Unreamed Humeral Nail (UHN) (Synthes, Betlach, Switzerland) and the Telescopic Locking Nail (TLN) (Stryker-Trauma, Schönkirchen, Germany) each have a specific compression system. Both implants have been used in clinical practice with good results (Goessens et al. 1996, Blum et al. 1998, Rommens et al. 1998, Verbruggen et al. 2002). In this study, we compared both nails concerning their stability against bending and torsion both with and without compression. To our knowledge, this is the first study to compare humeral compression nails.



Figure 1. The UHN (left) and TLN (right). The UHN is available in 6.7-, 7.5- and 9.0-mm versions; length varies from 190 mm to 325 mm. The TLN is available in one diameter only; length varies from 185 mm to 310 mm. Locking options are visible.

Material and methods

8 pairs of humeri were harvested from 8 fresh frozen human cadavers. To minimize variations in measurement, a strictly paired set-up was used to compare both nails. UHN and TLN were randomly assigned to the left or right humerus of the same individual.

Implants (Figure 1)

The UHN is a solid titanium nail. We used the 7.5-mm version. Compression is given through an external screw, which is mounted on the insertion handle. After tightening of this screw, static locking through the aiming device is necessary to maintain compression.

The TLN is a straight nail of stainless steel. The proximal and distal parts of the nail have a diameter of 9 mm to allow the use of strong 4.5-mm locking bolts. In the central section of the nail, the diameter is reduced to 7.6 mm to obtain the necessary elasticity needed for introduction and fracture healing. Compression is applied with an axial set screw.

Specimen preparation

All humeri underwent a DEXA scan to assess bone mineral density (BMD), and radiographic examination to exclude lesions that could influence measurements. Before testing, the humeri were thawed overnight at room temperature. Proximal and distal ends were embedded in polymethylmethacrylate (PMMA) (Figure 2). During embedding, the introduction site for the nail at the distal end of the humerus was kept free with

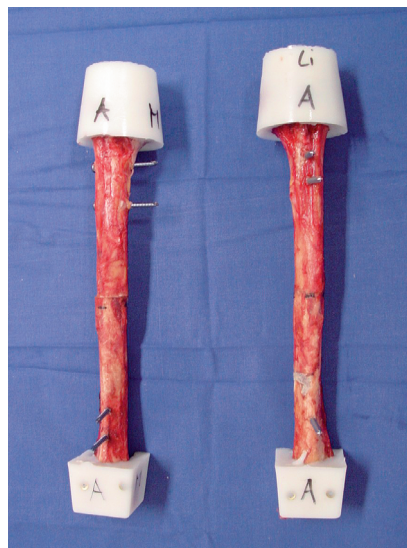


Figure 2. A pair of humeri after embedding in PMMA, osteotomy and implantation of nails.

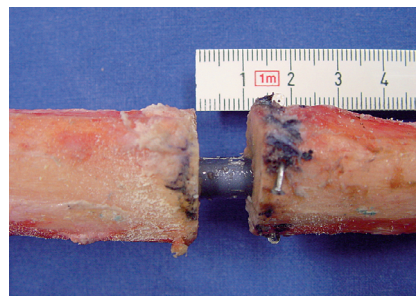


Figure 3. The bone defect created midshaft, simulating an unstable fracture.

a piece of foam rubber to allow later introduction of the nails.

After testing of the intact humeri, a midshaft osteotomy was set and the nails were introduced retrograde following the manufacturer's instructions. In the case of the TLN, power reaming to a diameter of 11 mm was used prior to implantation. After interlocking, compression was applied.

After the first tests, a circumferential bone defect of 10 mm was created proximal to the original osteotomy (Figure 3). Bending and torsional tests were run again.

Testing

All specimens were loaded through a rotation motor and a linear motor of a servo-pneumatic-operated machine (SincoTec, Clausthal-Zellerfeld,

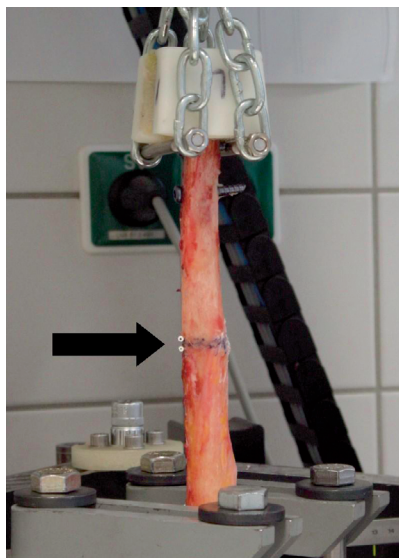


Figure 4. Testing of compression force through axial distraction with a force up to 1,500 N. Arrow indicates marking points.



Figure 5. Torsional testing with a torsional moment of 6.5 Nm.

Germany). The data from the work of the motors were registered with the PC program DasyLab (www.dasylab.com).

To assess compression forces exerted by the nails, axial distraction was applied with a force varying from 0 to 1,500 N. The opening of the osteotomy under distraction was captured by a video-analysis system using two marking points placed on both sides of the osteotomy (Figure 4). By analyzing the relative movement of these points with the video system, the opening of the osteotomy could be calculated. As the video was synchronized with the testing machine, the precise moment of opening and the corresponding force could be determined. This force is equal but opposite to the compression force. To test stability of the compression, the distraction test was repeated after the other tests had been completed.

For torsional stiffness, torsion in the humeral axis was applied with four sinusoid cycles of 0.5–6.5 Nm with a frequency of 0.1 Hz (Figure 5).

Bending stiffness (Figure 6) was determined with 4-point bending in 4 directions. The force was centrally applied with 4 sinusoid cycles of 10–1,000 N with a frequency of 0.1 Hz. With the bearings shifted over 0.03 m, this gave a bending moment of 15 Nm. The mean of the results over the four directions gave the main outcome. The constructs

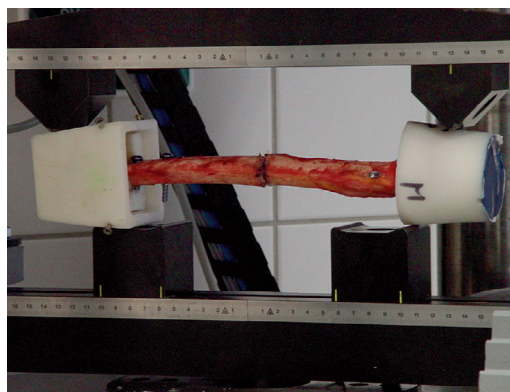


Figure 6. Four-point bending with a bending moment of 15 Nm.

with a bone defect were tested under torsion and bending only.

Endurance testing in bending of the nail-bone constructs with compression was done through cyclic loading in the medio-lateral direction with 100 cycles as described above. Endurance testing in torsion, also with 100 cycles, was done during torsional testing of the constructs with a bone defect.

Statistics

Results of each pair of cadaveric humeri from the same individual were analyzed using Student's t-

Table 1. Mean (SD) opening of the osteotomy in mm before and after cyclic loading under axial distraction with 1,500 N

	Opening of osteotomy (mm)		Difference (95% CI) ^b	P-value
	TLN	UHN		
Before cyclic loading	0.08 (0.03) ^a	0.23 (0.17) ^a	–66% (–89% to 3%)	0.1
After cyclic loading	0.10 (0.06) ^a	0.31 (0.18) ^a	–67% (–84% to –37%)	0.01

^a Geometric mean.
^b Because of log-normalization, differences and CI are expressed as percentages.

Table 2. Mean (SD) bending stiffness, in kN/mm, of nail-bone constructs and intact humeri with loading of 15 Nm

	Bending stiffness in kN/mm		Difference (95% CI)	P-value
	TLN	UHN		
With compression	0.96 (0.25)	0.80 (0.25)	0.16 (0.07 to 0.25)	0.01
With gap	0.61 (0.08)	0.57 (0.11)	0.04 (–0.01 to 0.08)	0.2
Intact humeri	1.05 (0.22)	1.05 (0.25)	0 (–0.08 to 0.07)	0.9

test for paired analysis. Level of significance was set at $p < 0.05$. In cases where the results were not normally distributed, they were log-normalized and the geometric mean was calculated. 95% confidence intervals (CI) were determined.

Results

Intact humeri

The mean BMD for the left humerus was 0.41 (SD 0.11) g/mm³ and for the right humerus it was 0.42 (SD 0.12) g/mm³ (difference = –0.01, 95% CI = –0.02 to 0.01; $p = 0.3$). Intact humeri had a mean bending stiffness of 1.03 (SD 0.22) kN/mm for the left side and 1.07 (SD 0.25) kN/mm for the right side (difference = –0.04, 95% CI = –0.11 to 0.03; $p = 0.3$). Mean torsional stiffness for the left side was 1.64 (SD 0.55) Nm/° and it was 1.79 (SD 0.76) Nm/° for the right side (difference = –0.15, 95% CI = –0.35 to 0.05; $p = 0.2$).

Axial distraction (Table 1)

Under axial distraction, deformation in the osteotomy was less in the case of the TLN than in the case of the UHN. The difference, however, was not statistically significant. After torsional testing and bending tests with cyclic loading in the mediolat-

eral direction, the deformation in the constructs with UHN was significantly more than in those with TLN.

Bending (Table 2)

Under compression, the constructs with TLN are significantly stiffer than those with UHN. In the constructs with a bone defect, this difference was not significant. After cyclic loading in the mediolateral direction, no significant differences in deformation were found (Table 4). The nail-bone constructs with the TLN under compression in bending reached 91% of the stiffness of the intact humeri, as compared to 76% for the UHN. For the constructs with a bone defect, this was 60% for both nails.

Torsion (Tables 3 and 4)

In torsional testing under compression, the TLN was more stiff than the UHN. The difference, however, was not significant. Also, with bone defects both nails were comparable in torsional stiffness (Table 3). After cyclic loading, no significant differences in deformation were found (Table 4). In torsion, the constructs with TLN had 78% of the stiffness of the intact humeri and the UHN had 72%. For the constructs with a bone defect, this was 50% for both nails.

Table 3. Mean (SD) torsional stiffness, in Nm/°, of nail-bone constructs and intact humeri with loading of 6.5 Nm

	Torsional stiffness in Nm/°		Difference (95% CI)	P-value
	TLN	UHN		
With compression	1.21 (0.32) ^a	1.09 (0.42) ^a	11% ^b (–18% to 50%) ^b	0.5
With gap	0.91 (0.26) ^c	0.85 (0.24) ^c	0.06 (–0.02 to 0.15)	0.2
Intact humeri	1.72 (0.61)	1.71 (0.71)	0.01 (–0.22 to 0.24)	1.0

^a Geometric mean.
^b Because of log-normalization, difference and 95% CI are expressed as percentages.
^c Mean of 7 pairs; 1 pair broke during initial torsional testing.

Table 4. Mean (SD) deformation of the nail-bone constructs after cyclic loading in bending and torsion

	Deformation after cyclic loading		Difference (95% CI)	P-value
	TLN	UHN		
Bending (mm)	0.42 (0.14)	0.48 (0.23)	–0.06 (–0.21 to 0.08)	0.4
Torsion (°)	1.52 (0.56) ^a	1.66 (0.80) ^a	–0.14 (–0.70 to 0.41)	0.7

^a Mean of 7 pairs; one pair broke during initial torsional testing.

Discussion

We compared two humeral intramedullary compression nails regarding their stability against torsional and bending forces. We assumed that there are no differences between the left and right bones of the same individual, and we found no significant differences in bone mineral density and stiffness in 4-point bending and torsion in the humeri.

We decided on a strictly paired analysis with random assignment of the nails to left or right humerus, as described by Blum et al. (1999, 2000). Other paired analyses that have been published have compared more than two implants using the same bone twice or more, and have used nail types with various cross-sectional diameters (Henley et al. 1991, Dalton et al. 1993, Schopfer et al. 1994, Zimmerman et al. 1994, Mølster et al. 2001). This leads to comparison of groups with smaller numbers, which can compromise statistical calculations.

The midshaft transverse osteotomy we used simulates an unstable fracture type with small contact area, which is preferentially operated and in which compression improves fragment adaptation and stability. Fracture of the humeri by bending or

torsion might create fracture types not suitable for compression. Furthermore, a transverse osteotomy is easy to reproduce. A bone defect simulates a worst case scenario of a highly unstable fracture. The influence of contact between bone fragments in bending and torsion is eliminated. The stability of the constructs is then mainly determined by the bone-bolt and nail-bolt interface. In this way, the implants are tested as two extremes of different situations possible in vivo: on the one hand a model allowing full bone-to-bone contact with maximum transfer of load and no loading of the implant, on the other, no bone-to-bone contact with no transfer of load and maximum load on the implant (Tencer et al. 1984, Bankston et al. 1992, Lin et al. 1998).

In compressing the fracture, contact between both fragments is restored with a certain force. The exact compression needed for optimal bone healing is, however, not known. It is also very difficult to quantify. At the osteotomy, differences in contact area remain and depending on the intramedullary position of the nail, apposition of fragments may need greater or less effort. Thus, pressure gauges or a torque screwdriver are not useful. Blum and Rommens (2000) used the metric scale on the compression device of the UHN. The limit-

ing factors here are the strength of the locking bolt and bone. Application of compression until the nail has migrated over a certain distance—regardless of the torque applied—may lead to bending or cutting out of the locking bolt. Thus, in our study we applied compression as in the clinical situation, by the feel. The surgeon turns the screwdriver until the fracture gap is closed and maximum resistance appears. Bühren (2000) compared the torque required with that in tightening of a well-fitting cortical screw. As the feel of maximum torque is obvious, and the nails were implanted by the same person with clinical experience of these implants, variation in compression is limited. This constitutes a weak point in our study, but it seemed the best compromise between scientific accuracy and feasibility.

We did not find a significant difference in opening of the osteotomy under distraction. The compression applied was similar for both nails, and more than 1,500 N, which is considered sufficient for a stable osteosynthesis (Perren et al. 1969, Kaessman et al. 1974, Ritter et al. 1982, 1987). After cyclic loading, opening of the osteotomy with the TLN was significantly less pronounced than with the UHN. With the latter, some compression is lost because of the play of the locking screws in the locking holes. Locking of the screw in the oblong hole with an axial set screw leads to angular stability, which explains the higher stability of the construct. In their experiments with a femoral compression nail using an axial set screw, Mittelmeier et al. (1990) also found that cyclic loading affected compression only minimally.

The TLN was significantly stiffer in bending than the UHN. No significant differences in torsional stiffness were found. We considered the compression over the fracture sufficient to withstand the torsional forces acting on the humerus under physiological conditions. This is in accordance with the findings of Schopfer et al. (1994) that, for stability in torsion in a transverse fracture, the contact provided at the fracture site is more important than the diameter of the nail.

In the unstable fracture simulation both in bending and torsion, no implant appeared superior. Also, cyclic loading did not lead to significant differences in deformation. The forces applied lie well within the elastic region of the implants.

In bending, the TLN under compression reached more than 90% of the stiffness of the intact humerus, and the UHN reached 78%. In torsion this was 78% and 72%, respectively. As compared to the Russell-Taylor Nail (RT), which reached only 20% as described by Schopfer et al. (1994), both TLN and UHN implants are true load-sharing devices. There is no risk of stress shielding as with a plate, which can reach a stiffness of about 150% of that of the intact humerus (Waite et al. 1991).

Comparison of our results with those of other biomechanical studies on interlocking humeral nails is difficult. Several implants are often tested and the methods, forces applied and calculations are not always described (Lewis 1997). Seidel nails (SN) were found to be as stable as double-locked nails both in bending and in torsion (Henley et al. 1991, Dalton et al. 1993). According to Schopfer et al. (1994) and Zimmerman et al. (1994), double-locked nails were significantly stiffer in torsion than the SN. In the study of Blum et al. (1999, 2000), the RT was less stable in torsion than the UHN because of the initial rotational instability from the play of the distal locking bolt. This varies between 4° and 30° (Zimmerman et al. 1994, Mølster et al. 1997, Blum 1999, Blum and Rommens 2000). The intrinsic instability of RT and SN was shown in the study of Mazirt et al. (1999). The primary instability of the SN, RT and ACE nail was explained by the “play” of the different locking systems. According to Henley et al. (1994), the plate is more stable in torsion. In the analysis of Zimmerman et al. (1994), the plate was stiffer than all nails in bending and stiffer than all nails except the Orthofix nail in torsion. Torsional stiffness of the nail-bone constructs under compression for UHN (1.20 Nm/°) and TLN (1.26 Nm/°) (values before log-normalization) were comparable with the stiffness of 1.27 Nm/° of the DC plate as measured by Zimmerman et al. (1994), and 1.37 Nm/° as measured by Henley et al. (1991). These were, however, the maximal values reached at the yielding point of the construct under destructive torsion. Our values lay well within the elastic zone of the constructs.

As for every in-vitro biomechanical study, our study also has its drawbacks. We did not take the stabilizing role of the soft tissues into account (Sarmiento et al. 1977, Latta et al. 1980, Bühren

2000). A comminute, unstable fracture is not just a defect. Bone fragments in combination with soft tissues may still allow some transfer of load. With a reamed nail, reaming debris might also have a stabilizing effect. Furthermore, as the forces acting on the humerus in everyday life are not known, assumptions have to be made in in vitro testing. Both implants were, however, tested under identical circumstances in a paired set-up. Thus, conclusions can be drawn concerning the inherent bending and torsional properties of these implants in combination with bone.

Contributions of authors

JV: developed the idea for this study, wrote the protocol, and raised the funds. Together with WS, who operated the testing machine and was responsible for data acquisition, he performed all tests. JB: coordinator of the laboratory, critically evaluated the protocol and gave advice during the actual tests, based on his own experience with biomechanical studies. PR: director of the Trauma Department of the University Hospital Mainz and conceived and developed the UHN. JS: formal head of the Trauma Department of the University Hospital Maastricht, conceived and developed the TLN. Both senior authors supervised the study.

This study funds were received from two companies that were otherwise not involved in the study. Both companies, Stryker and Synthes, provided us with an equal amount of financial support and supplied us with the necessary implants and instrumentation. The companies were not involved in the conception and design of the study, the collection, analysis and interpretation of the data and the writing of the manuscript.

Furthermore, both senior authors have developed the implants tested.

Stapert developed the Telescopic Locking Nail with Stryker, and Rommens developed the Unreamed Human Nail with Synthes.

This did guarantee an impartial evaluation of the tests.

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