

A new device for external fixation

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Using a ball-and-socket joint model, the optimal mechanical design of a simple universal ball joint was established. The maximum resistive moment was 70–72 Nm for a tightening torque moment of 5 Nm, their ratio being 14. The corresponding ratios for the Hoffmann universal ball joint and Orthofix® are 1.0–4.3 and 1.1–1.6, respectively. A complete unilateral frame consists of two ball joints and one square connecting tube. Full-frame behavior under external loads was tested in the three principal planes and in torsion. Compared with a Hoffmann quadrilateral system, the new system was four times more rigid in the anteroposterior plane, similar in axial load and lateral bending, and 64 percent more rigid in torsion.

Many external fixation systems have become complex and clumsy in order to prevent pin deformation (Knutson et al. 1984) or because of low mechanical efficiency of the adjustable components (Rothacker and Gabanella 1983, Finlay et al. 1987). Only a few systems allow for pin insertion in a plane parallel to the joint surface in juxtaarticular fractures without additional components (Edwards 1983, De Bastiani et al. 1984). The ideal pin clamp should be attached to a simple universal ball joint that permits pin insertion from 0 to 360° in any plane and in any such position allows for angulation of pins in any direction. To overcome the problem with low mechanical efficiency of existing ball joints, a developmental program was started in 1976. After extensive mechanical research and clinical evaluation, the optimal design of a simple universal ball joint was established. The maximum resistive moment of this ball joint provides adequate rigidity for unilateral application, no matter what type or location of injury.

Materials and methods

In a preliminary mechanical testing series using a ball and socket joint model, the effect of the size of the contact area between the ball and the sockets on the maximum resistive moment was studied (Figure 1). By gradual decrease of the contact area down to a near linear circular interface, the maximum resistive moment was increased. During these experiments, the hardness of the materials in the ball and the sockets was kept constant. By increasing the hardness of the sockets, the maximum resistive moment was further increased.

The final design of the universal ball joint consists

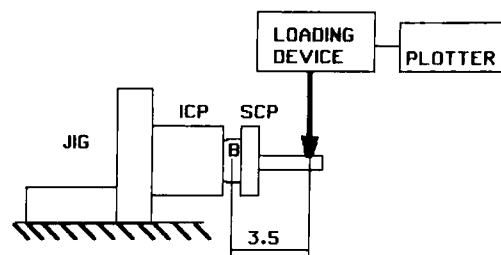


Figure 1. The ball and joint model is fixed to a specially designed jig. Load is applied perpendicular to the central axis of the swivel ball at a distance of 3.5 cm from the center of the ball. Registration of applied load is recorded on a plotter and gradual increase of load is continued until slippage.
ICP = Inferior compressing plate.
SCP = Superior compressing plate.
B = Spherical ball secured between ICP and SCP.

of two compressing plates made of an aluminum alloy (Figure 2); a complete basic set includes two ball joints and a connecting tube of different lengths (25, 30, and 35 cm). The external tube is connected at both ends to each swivel ball by a tube-clamping device. If one of these clamping devices is unlocked, the frame is converted from a static to a dynamic state.

Full-frame behavior under different modes of loads (anteroposterior, axial, and lateral bending) was determined in a three-point bending test model (Figure 3) with a fixed-beam length using a bone model of reinforced aluminum tubes (Hammer and Helland 1987). The deformation rate was standardized to 3.2 mm/min. Load was applied up to a maximum of 500 N with an Alvetrone materials testing machine (Alvetrone TCT 10, Lorentzen, Wettre, Stockholm, Sweden). The torque moment used to tighten the ball joint was standardized to 5 Nm, which is easily reached with a conventional screw driver operated with one hand. In the present investigation, three half pins with a diameter of

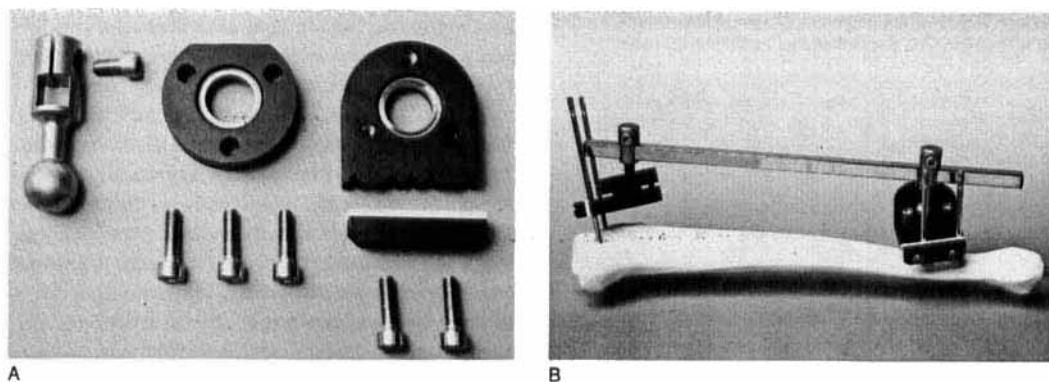


Figure 2.

A. Dismantled universal ball joint. The ball is located at one end of a 5-cm solid pillar made in one piece (top row, left). This swivel ball is introduced from the inside of the superior compressing plate (top row, middle) and by tightening one of the three compressing screws, the ball can be secured in an elective positioning. In the center of each of the compressing plates is a hardened stainless acid-proof steel ring inserted and secured by forced fit. The pin retainer, which is a part of the inferior compressing plate (top row, right) can hold five pins with a diameter varying from 4 to 6 mm in different positions (bottom row, right). The maximal pin distance within one group of pins is 44 mm.

B. Complete frame mounted on a fractured plastic bone model of the tibia. The universal ball joints allow for pin insertion in any plane 360° around the axis of the swivel ball. In any such position the compressing plates with the pin retainer can be angled a total of 64° in any direction.

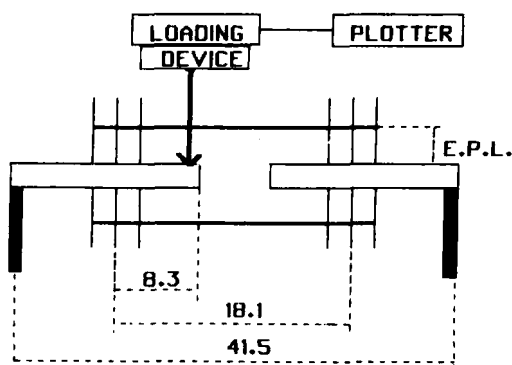


Figure 3. Principal drawing of the three-point bending test set-up.

E.P.L. = Effective pin length.
Measures in centimeters.

5 mm were used (cat. no. GM 221204OH, Jaquet Orthopedie S.A., Geneva, Switzerland). For comparison, a conventional Hoffmann-Vidal frame (Jaquet Ortop. S. A.) was analyzed in an identical way with three 4-mm transfixation pins in each fragment. Because the manufacturer of the Hoffmann device does not provide recommendations about what torque moment should be used when the universal ball joint is tightened, this had to be examined prior to the three-point bending test in a separate experiment. A torque moment of at least 11 Nm had to be used to prevent early displacement particularly around the longitudinal axis of the side bars during load. Based on clinical experience, the distance from the bone surface to the pin clamp (effective pin length) was set at 9 cm when the Hoffmann frame

was tested; the distance varied between 1 and 2 cm when the new system was analyzed. To prevent uncontrollable asymmetric behavior of the quadrilateral device under load, the effective pin lengths on the lateral and medial sides of the fracture model were identical. Torsional rigidity was analyzed in a separate experiment described elsewhere (Hammer and Helland 1987).

Results

When the partial spherical interface design was tested, the maximum resistive moment never exceeded 24 Nm. To displace this ball joint, a force of 480 N had to be applied. The mechanical design was dependent on three different parameters that had to be optimized individually and in combination. First, the relationship between the diameters of the socket and the ball had to be in the range 0.90–0.92. Secondly, the socket had to be at least 1.2–1.7 times harder than the ball. Thirdly, the contact area between these two parts had to be near linear circular (Swedish Pat. no. 8502124–3). When the final design was tested, the maximum resistive moment was 70–72 Nm. The ratio maximum resistive moment/torque moment for this ball joint was 14.0–14.2. The corresponding ratios for the Hoffmann universal ball joint and Orthofix® are 1.1–4.3 (Schröder 1985) and 1.1–1.6 (Chao and Kasman 1984), respectively.

Repeated tightening of the ball joint up to 500 times did not reduce the maximum resistive moment. The clamp of the pin retainer was tightened 100 times with

Table 1. Rigidity in N/mm (mean, SD) when frames were mounted with all the pins parallel and in the horizontal plane

	Effective pin length (cm)	Axial		Lateral		AP	Ratio AP/lateral
Hoffman	9	93	7	83	7	16-1	0.2
Hammer	2	75	6	29	1	32-2	1-1.2
Hammer	1	151	17	55	4	66-5	1-1.4

a torque moment of 15 Nm on each of the two screws for a total of 30 Nm. In this test, two 5-mm pins were inserted in the outer pin grooves. No signs of fatigue were observed, and the residual deformation of the clamp was less than 0.05 mm. The rigidity, expressed as N/mm, was calculated from the slope of the load/displacement curve simultaneously recorded on a plotter during three-point bending tests (Table 1). When the maximum 500 N load was applied in the anteroposterior plane, the rotational moment acting on the new ball joint was 64 Nm (Figure 3). There was no detectable slippage of the ball joint, but a residual displacement of the fracture model was noted.

Repeated application of maximal load revealed that this residual displacement of 3 ± 3 mm (mean $\pm$ SD) was caused by a slippage of the pins within the pin clamp. The largest slippage (6 mm) was always observed for the pin most remote from the fracture gap. Based on these findings, the pull-out strength of the pins from the clamp was calculated to be within the range 850-930 N. The Hoffmann frame had a torsional rigidity of 4.6 ± 0.4 Nmm vs. 7.5 ± 0.2 Nmm for the new device ($P < 0.001$).

Discussion

If a partial spherical interface is used in the design of adjustable components, the compression force applied to the sockets will be distributed over a large contact area on the surface of the ball. The resulting point surface pressures, and as a consequence the surface friction forces, will be low. To reach an acceptable magnitude of maximum resistive moment, increased compression forces must be applied (Chao and Kasman 1984, Youm et al. 1986) with risk of jeopardizing the mechanical integrity of the adjustable components. The manufacturer of the Orthofix[®] dynamical axial fixator recommends partial replacement of the ball-joint mechanism after it has been used on 3-5 patients. This does not seem to be a problem with the Hoffman universal ball joint, but the rather low mechanical efficiency requires a compensatory increase in tightening forces. The torque moment of 11 Nm, which had to be applied to avoid early displacement of the Hoffmann frame, is identical to figures of Youm et al. (1986),

who determined the amount of tightening of components of frames on patients using a torque wrench and found a wide variation, from 3.3 to 12.1 Nm.

Improved mechanical characteristics of the adjustable components simplify the external fixation system. The maximum resistive moment is primarily a measure of the mechanical efficiency of the ball joint against dislocating forces. In the three-point bending test, however, rotational forces of the same magnitude (64 Nm) were applied to the ball joint when anteroposterior rigidity was determined. The ratio between anteroposterior and lateral rigidity in the Hoffmann system is 0.2 and the corresponding value for the new frame is 1.1-1.4. This may be important clinically particularly in fractures of the tibial shaft (Fick 1911, Paul 1980, Behrens et al. 1983). Conclusions drawn from animal experiments suggest that the loading frequency and the magnitude of micromovements at the fracture site should be limited (Kenwright et al. 1986). Using a transverse tibial osteotomy in sheep, Kenwright et al. (1986) found that controlled axial micromovements at the fracture site of 2 mm was detrimental to the rate of healing, whereas 0.5-1 mm enhanced mineralization and fracture stiffness.

Clinical fracture series support these experimental findings, no matter if early micromovements are applied with a mechanical device (Kenwright et al. 1986) or are an effect of biological compression during weight bearing in a dynamized (De Bastiani et al. 1984) or destabilized (Burgess et al. 1986) external fixation system. Therefore, it seems logical that the overall rigidity of an external fixation device should neutralize the principle forces acting on an injured limb during the early period of bone and soft-tissue consolidation. In addition, the construction of the frame should allow for reduction of the rigidity during the healing process (De Bastiani et al. 1984, Burgess et al. 1986, Gotzen et al. 1986, Hammer and Helland 1987, Finlay et al. 1987). Stabilization of tibial shaft fractures with a unilateral single-bar Hoffman frame, as an elastic or flexible external fixation, has been advocated (Burny 1979). However, the low rotational rigidity of this simple frame (Finlay et al. 1987) limits its use. In a series of 34 tibial fractures (Schmidt and Rorabeck 1983), stabilized by a single Hoffmann half-frame, the initial reduction was lost in 5. In all of these 5 patients, at least 1 of the pin groups was farther than 5 cm from the most proximal or the most distal extent of the fracture. In complex injuries, therefore, a more complex Hoffmann frame is necessary (Huiskes and Chao 1986). Vidal et al. (1983) and Edwards (1983) recommended a complementary anteroposterior anchorage with half pins to compensate for low anteroposterior rigidity. A similar, but modified frame was advocated by Knutsson et al. (1984).

However, full-frame configurations tested experimentally may differ from the clinical situation where important anatomic structures and/or soft-tissue injuries limit the selection of pin-insertion sites. It seems, therefore, reasonable to aim at a less complex external configuration, provided that the requirements for acceptably rigid immobilization are met (Mooney and Glaudi 1982). Our new simplified system does meet the basic mechanical requirements and is approximately as rigid as the Hoffmann-quadrilateral system in axial and lateral bending and superior in the AP plane. The versatility of the new ball joint allows for a larger number of possible pin-insertion planes and fa-

cilitates stabilization of juxtaarticular fractures. This new system allows for a reduction of the effective pin length; and in a fracture of the tibial shaft, the ratio of AP to lateral rigidity can be varied between 1.4 (parallel insertion of both pin groups in the horizontal plane) and approximately 8 (all pins parallel in the AP plane). In addition, a unilateral configuration provides a good wound access, is simple to apply in the emergency situation, avoids transmuscular pinning with the well-known side effects, and increases the comfort and mobility of the patients. Preliminary studies in 56 patients confirm the usefulness of this new fixation device.

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