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Fracture stiffness measurement using the orthometer: reproducibility and sources of error

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Abstract

Objectives. To elicit the reproducibility and the common sources of error in the use of the Orthometer, a commercially available goniometer based system, designed to measure the stiffness of healing fractures.

Design. A laboratory based study.

Background. The Orthometer is widely used to measure the progress of fracture healing in a quantitative manner. It has been shown previously that the bending stiffness of a fracture increases with healing and that a stiffness of 15 Nm/degree equates with the functional union of a tibial fracture.

Methods. The Orthometer was attached in a standard manner to nylon bars of known stiffness to determine the accuracy of the device. The Orthometer was then set up with changes in a single positional variable to assess the effect of this variable on the measurement accuracy. A number of different clinicians were asked to use the Orthometer before and after a simple training session and any improvements in the measurement accuracy were observed.

Results. Stiffness could be measured to within 10% or less of the true stiffness. Markedly different degrees of error were introduced with the various set-up variables. A simple training session improved clinician accuracy.

Conclusions. Although the Orthometer does allow some degree of safety margin, it is essential that set-up is performed carefully, and that the clinician has been trained in the use of the device.

Relevance

Quantitative measurements of fracture healing have enormous potential benefits over manual and radiological methods of assessments. Provided these are carefully performed, the accuracy of these measurements is good.

1. Introduction

The point at which a tibial fracture is healed has never been officially defined, but it is assessed in any number of different clinical, radiological and mechanical ways. Manual assessment is very subjective and shows poor accuracy [1], as do plain radiographs [2]. The measurement of fracture stiffness has been shown to accurately determine the functional union of a tibial fracture at a bending stiffness level greater than or equal to 15 Nm/degree, ≈25% that of the intact bone [3] and correlates with absolute strength during progress towards union [4]. Fracture stiffness can be measured directly using the Orthometer (Orthofix, SRL. Verona. Italy), which consists of a central electronic goniometer with two limbs emerging at 180° to each other, one being mobile in a single plane within a range of 30° either side of the neutral position. The goniometer attaches to the bone screws of an external fixator, the fixator having previously been removed (Fig. 1). The aim of this study is to assess the accuracy, reproducibility and potential sources of error produced by this device.

2. Methods

A series of nylon bars were prepared with known stiffnesses of 10–30 Nm/deg. in 5 Nm/deg. increments, these stiffness values being confirmed by testing the bars in four point bending. Two sets of three conical 6 mm pins (Orthofix SRL, Verona, Italy) were fitted to each

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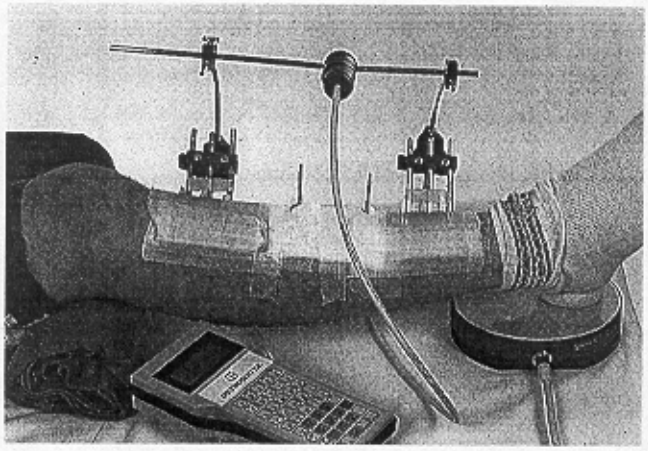

Fig. 1. The Orthometer in clinical practice.

bar. The goniometer was fitted to these pins, with the proximal limb of the device securely clamped, the distal limb sitting unrestrained in a containment ring. The standard set up procedure, as described in the manufacturers manual, was used throughout the study. This includes positioning the pivot point of the goniometer vertically over the fracture site, checking the goniometer is horizontal in relation to its rotational axis, and ensuring that the limbs of the device lie in horizontal alignment, parallel to the bone. The nylon bar was supported proximally to mimic the knee bolster used in clinical practice, and the distal end was placed on the force plate supplied with the Orthometer, mimicking the heel of the patient (Fig. 2). The mid-point between the two sets of pins was assumed to be the 'fracture site'. With the goniometer positioned centrally between the two sets of pins, a deflecting force was applied to the bar at the mid-point, and a series of five stiffness readings per bar were obtained. The 10 Nm/deg. bar was then used to test reproducibility by repeated testing after set up and disassembly of the device, initially by the author (intra-observer), and then by a number of senior orthopaedic trainees (inter-observer). Finally, sequential and deliberate changes in the set-up variables of the Orthometer were made to elicit the relative effect of these variables on the accuracy of the readings. The variables tested were longitudinal angulation, misplacement of the goniometer relative to the central point (or 'fracture site'), misplacement of the applied force relative to the central point, rotation of the goniometer about its central axis, and alternate positions of the goniometer with relation to the bar.

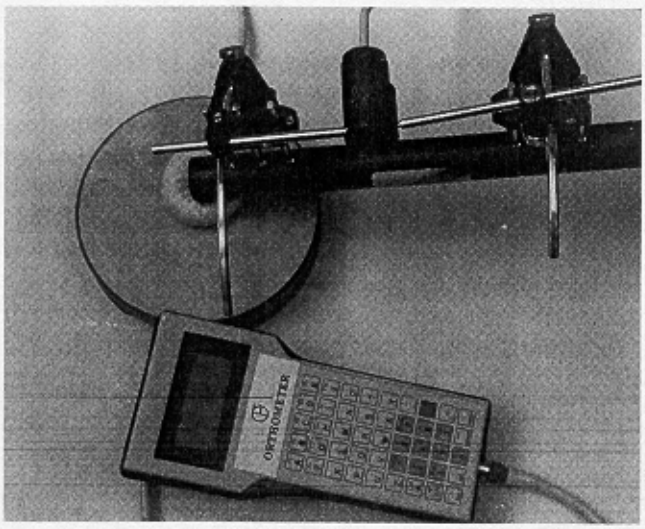

Fig. 2. The Orthometer attached to the fixator pins on nylon bar.

3. Results

The stiffness results obtained using the Orthometer remained within ±10% of the actual stiffness for all of the bars tested, when no set up variations were introduced, and using a single, trained observer. With increasing stiffness, the accuracy did steadily deteriorate, from an error of ±0.54 Nm/deg. at 10 Nm/deg. (5.4%), to ±2.2 Nm/deg. at 30 Nm/deg. (6.8%). Intra-observer error was a maximum of 2.2% with a single clinician, whereas when a number of observers were employed, inter-observer errors were on average 6.3%.

The variables introduced during set up had a wide ranging effect on the degree of error they introduced. In descending order of potency these were:

- angulation of the goniometer in the longitudinal plane(sag) gave errors up to a maximum of 22%, worsening as the angulation increased;
- goniometer mal-position in relation to the fracture gave errors of 11% per cm off centre;
- mal-position of the applied force with relation to the central point ('fracture site') gave an error of 1% per cm off-centre;
- rotation about the axis, rate of application of force and alternate goniometer position in relation to the bar (i.e. by the side, but with normal set up otherwise) gave errors of less than 1%.

4. Conclusions

It is clear from the results that relatively minor variations in positional set-up can give errors of up to 22% of the actual value in stiffness readings. Provided the goniometer is carefully set up, with no intentional variables introduced, the maximum error encountered is around 6.8%. With an intentional error introduced, this rises to 22%, depending on the particular variable applied. Longitudinal mal-alignment (sag) was the most potent source of error, followed in descending order by mal-position of the goniometer pivot point with relation

to the fracture (11% error per cm mal-position), mal-position of the applied force (1% error per cm mal-position), and then rotation about its axis and rate of force application, which gave only small (<1%) errors.

The next most important aspect of measurement from a clinical standpoint is intra- and inter-observer error. Predictably intra-observer error was much less than inter-observer, but both fell well below 10%, and again remain within satisfactory limits. The only caveat to this point is that a 'fresh' investigator should have a basic training session in use of the device, as when one of our test subjects missed this session, his accuracy was found to be >10%, but this reduced to 5.4% with simple pre-test tutoring. Ideally, a single observer should take serial readings for an individual patient, but if this is impossible, then an adequately trained substitute should not produce significant errors. Set up of the device should be careful and the variables introduced above must be avoided at each new reading.

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