Abstract

**Background:** Orthopaedic traction tables are used as an aid in numerous surgical procedures. The present paper aims to present a prototype of an external device of lower limb traction, which is portable, of simple construction, and can be installed on any operating table, with possible application in surgical and teaching practices. We will compare the quality of radiographic images obtained with the help of this prototype (PT) to those images obtained with the aid of the conventional traction table (CT).

**Materials and Methods:** Cross-sectional, observational, and double blind study, approved by the Research Ethics Committee. On two occasions 36 randomly selected radiographs of the lower limbs, 18 of which obtained on the CT and the remaining on the PT, were evaluated by nine physicians. These radiographs were obtained from three volunteer and none of them presented musculoskeletal system disorders previously diagnosed in the study. Examiners rated each picture from 1 to 5, according to the quality of the image obtained. The responses were submitted to statistical analysis by SPSS®, v23. Comparisons were considered significant when \( p < 0.05 \), with a 95% confidence interval.

**Results:** The average ratings were similar and all significance tests between the averages were higher than 0.9. The intra-observer agreement was 76.13% for the PT and 82.69% for the CT. The inter-observer agreement was low for both models. Due to its lower weight and smaller size compared to the CT and the material used for prototyping, the production cost of the PT is quite affordable.

**Conclusions:** The PT presented in this paper is a good alternative to CT.

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**Keywords**

Traction Table; Fracture Table; Orthopaedic Surgery, Orthopaedic Prototype; Lower Limbs.
Introduction

The use of traction tables (TT) in the diagnosis of orthopaedic trauma surgery has been reported since 1927, when Ranking described a model in a scientific paper [1]. The early models were quite versatile, allowing the traction of the spine and upper and lower limbs [2].

Currently, the TT is used as an aid in various procedures, especially those involving the lower limbs such as hip arthroscopy and osteosynthesis of femoral fractures [3-11].

The use of TTs is still restricted to some services because of their limited availability and the often lack of familiarity on the part of doctors. In addition, their use is not exempt from risk and numerous complications have been described, such as damage to soft tissues and neurological damage [12-16].

The traction table can provide the orthopaedic surgeon with many benefits, facilitating the implementation of some surgical procedures. However, the surgeon who intends to use a TT should know the potential dangers and a practical and easy way to use it.

Unfortunately, not every hospital offers the access to the use of a TT, much due to its costs and the difficulty to shift from a conventional operating table to a traction table.

A low cost model that is easy to move around would reduce complication associated with traction tables and would certainly facilitate the teaching of surgical techniques that require such a device.

This paper aims to present a prototype (PT) of an external device to be used with lower exterior limbs in procedures of the proximal femur, femoral shaft and knee, enabling vertical, horizontal and rotational lower limb stabilization, similar to that used in Fracture Table (CT). The device is portable, simple to manufacture and can be installed in any operating table.

At first, our goal is just to compare if it is possible to perform adequate intraoperative imaging on a patient comparing the prototype with a conventional traction table. If we reach our goal in this study, we can carry out further studies to prove the efficacy of the prototype device in terms of applying traction to a patient for surgery.

Materials and Methods

This cross-sectional, observational study, approved by the Research Ethics Committee, evaluated 36 selected radiographs in anteroposterior (AP) and lateral (L) incidence obtained with a C-Arm (OEC Fluorostar 7900 Compact - GE®) device. The radiographs were produced at Christus University Center in the city of Fortaleza – Brazil, in September 2016 and informed consent was obtained from all individual participants included in the study.

The traction table prototype (Figure 1 and 2) was used in 18 of the 36 images, while the remaining used the CT (MAQUET 1140 20A, with extension Frame®) (Figure 3). The images were obtained from three volunteers (12 images each) and correspond to three lower limb segments: proximal femur (PF), femoral shaft (FS) and knee (KN), all in two incidences (AP and L), totaling 36 images.

The study included three volunteer doctors, two men and a woman, aged 27, 40 and 52, respectively. None of them had diagnosed muscle skeletal system disorders, such as osteoarthritis or fractures, previously to the study. Everyone was aware of the risks of exposure to radiation image intensifier
and signed the Free Prior Informed Consent. The 36 tests were performed on the same day and evaluated the right lower limb, considered healthy by the researchers.

As measures and precautions taken to prevent the risks related to the study, the participants were subjected to x-ray examinations with lead protection of the neck, chest, abdomen and gonads. One of the researchers was always alongside the volunteers and ready to suspend the study if they so requested. In addition, all images were obtained with the C-Arm in fluoroscopy mode, with 54 kV and 1.28 mA.

Radiographic study images were acquired by digital file in JPEG format, directly extracted from the C-Arm by USB and transferred to an Apple iPad Pro®.

The images were evaluated by nine physicians: three orthopedists (ORT), three radiologists (RAD) and three orthopaedic residents of the 3rd year (RES). Examiners assessed the 36 images in a maximum time of two hours, and two weeks later conducted a second evaluation using the same amount of time. We called the period of the first evaluation T1 and that of the second T2. The order of 36 images in T2 was modified by simple randomization. The examiners did not have access to the ratings of their peers or to their own ratings in the previous period, nor did the researcher know which limb segments or which table (PT or CT) corresponded to the images being analyzed (double-blind).

Examiners rated each image from 1 to 5, as follows: 1- Poor Image; 2- Bad Image; 3- Reasonable Image; 4- Good Image; 5- Excellent Image. The examiners were told they were expected to evaluate the images taking into account the possibility of using them for guidance in a surgical procedure, rating them for their quality, clearness, and the presence of artifacts (radiopaque objects external to the patient, which hamper the analysis of imaging). Each examiner’s evaluation of the radiograph was recorded on a printed spreadsheet and sent to another researcher who had not participated in the process of obtaining the images or in the taking down the ratings in T1 and T2.

Categorical quantitative results are presented as percentages and counts and the numerical results in the form of central tendency measurement (simple description). The independent and paired average ratings were evaluated by using Student’s t-test.
with Bootstrap of 1000 samples and the Levene’s method of test for equality of variance and t-test for equality of means, in addition to the Pearson’s correlation analysis among paired measurements. They evaluated the repeatability and reproducibility of results through the intra-observer variation with the aid of a Gage R&R study, through multivariate ANOVA and inter-observer variations by using the Krippendorff’s alpha coefficient. Comparisons with p value of up to 0.05 and 95% confidence intervals were considered significant. The data were tabulated and analyzed by the SPSS (Statistical Package for Social Sciences), v23, SPSS Inc.

### Results

Using all (T1 and T2) ratings, we reached an average of 4.037 for the PT and 4.049 for the CT (Table 1). After the test of significance between these two samples (Table 2), we achieved a value of 0.944, which shows the non-inferiority of the PT compared to the CT, since the value was very close to 1.

Considering the ratings in T1 alone, we have an average of 3.907 for the PT, 3.913 for the CT (Table 1). In the test to evaluate the equality of means, we obtained a value of 0.981 (Table 2), showing that in the T1 phase there is also no statistically significant difference between the two tables.

### Table 1. Average score

| Model      | Period | Statistics | Bias | Standard error | Confidence interval 95% |
|------------|--------|------------|------|----------------|-------------------------|
|            |        |            |      |                | Inferior               | Superior                |
| Prototype  | T1 e T2| N          | 18   |                | 3.7632                 | 4.2805                  |
|            |        | Media      | 4.0370 | - 0.049       | 0.1303                 |                         |
|            |        | Standard deviation | 0.56076 | - 0.01875 | 0.06203 | 0.41404 | 0.64829 |
|            |        | Mean standard error | 0.13217 |          |            |          |          |
| Conventional | T1 e T2| N          | 18   |                | 3.8248                 | 4.2650                  |
|            |        | Media      | 4.0494 | - 0.0023      | 0.1111                 |                         |
|            |        | Standard deviation | 0.48950 | - 0.01744 | 0.05732 | 0.35357 | 0.58228 |
|            |        | Mean standard error | 0.11538 |          |            |          |          |
| Prototype  | T1     | N          | 9    |                | 3.5001                 | 4.3124                  |
|            |        | Media      | 3.9074 | - 0.0051      | 0.2008                 |                         |
|            |        | Standard deviation | 0.62485 | - 0.04220 | 0.11023 | 0.34170 | 0.76742 |
|            |        | Mean standard error | 0.20828 |          |            |          |          |
| Conventional | T1     | N          | 9    |                | 3.6222                 | 4.2056                  |
|            |        | Media      | 3.9136 | 0.0005        | 0.1484                 |                         |
|            |        | Standard deviation | 0.46656 | - 0.03453 | 0.08904 | 0.24523 | 0.60178 |
|            |        | Mean standard error | 0.15552 |          |            |          |          |
| Prototype  | T2     | N          | 9    |                | 3.8159                 | 4.4652                  |
|            |        | Media      | 4.1667 | 0.0020        | 0.1633                 |                         |
|            |        | Standard deviation | 0.48987 | - 0.04381 | 0.10111 | 0.22567 | 0.61125 |
|            |        | Mean standard error | 0.16329 |          |            |          |          |
| Conventional | T2     | N          | 9    |                | 3.8126                 | 4.4997                  |
|            |        | Media      | 4.1852 | - 0.0032      | 0.1653                 |                         |
|            |        | Standard deviation | 0.50000 | - 0.03935 | 0.09313 | 0.23938 | 0.62915 |
|            |        | Mean standard error | 0.16667 |          |            |          |          |
Table 2. Significance test.

| Period       | Levene’s test for Equal Variances | t-test for Equality of Means | Confidence interval 95% |
|--------------|-----------------------------------|------------------------------|------------------------|
|              | F       | Sig. | t     | df | Sig. (2-tailed) | Mean difference | Standard error difference | Inferior | Superior |
| T1 e T2      | 0.513   | 0.479 | -0.070 | 34 | 0.944          | -0.01235       | 0.17545               | -0.36889 | 0.34420  |
| T1           | 1.044   | 0.322 | -0.024 | 16 | 0.981          | -0.00617       | 0.25994               | -0.55722 | 0.54487  |
| T2           | 0.001   | 0.971 | -0.079 | 16 | 0.938          | -0.01852       | 0.23333               | -0.51315 | 0.47611  |

Levene’s Test to assess the equality of the average of notes of the table prototype compared to conventional.

Table 3. Paired average

| Period | Statistics | Bias     | Standard error | Confidence interval 95% |
|--------|------------|----------|----------------|------------------------|
|        |            | Inferior | Superior       |                         |
| T1     | Media      | -0.0041  | 0.1201         | 3.6791                 | 4.1420              |
|        | N          | 18       |                |                        |                      |
|        | Standard deviation | -0.01832 | 0.06360     | 0.38377                | 0.63889              |
|        | Mean standard error | 0.12609  |             |                        |                      |
| T2     | Media      | -0.0042  | 0.1083         | 3.9661                 | 4.3704              |
|        | N          | 18       |                |                        |                      |
|        | Standard deviation | -0.01619 | 0.05532     | 0.35030                | 0.56283              |
|        | Mean standard error | 0.11320  |             |                        |                      |

Student’s t-test: paired average of all notes (prototype + conventional) in two different periods (T1 and T2).

We applied the Levene’s Test to assess the equality of the average ratings of the PT compared to the CT.

When analyzing the ratings obtained in the second phase of the study (T2), we observed an average rating of 4.166 for the PT against 4.185 for the CT (Table 1). In the test to evaluate the equality of means in T2, we obtained a value of 0.938 (Table 2), showing that in T2, as well as in T1, there is no statistically significant difference between the two tables.

In paired tests, the ratings were compared in T1 and T2 for each evaluator individually. That is, the rating of a particular evaluator in T1 was compared with his own rating in T2. Thus, the paired evaluation of the 18 samples had an average of 3.91 (per evaluator) in T1 and 4.175 (per evaluator) in T2 (Table 3). The correlation coefficient obtained the r-value of 0.788 (a 0.520 to 0.943 range when used 95% confidence interval), which denotes a linearity in the increase of the average ratings in T2 in relation to T1 of moderate to strong positivity [p (sig) <0.001]. This increase in average in T2 was 0.265 (ranging from 0.099 to 0.431 when used 95% confidence interval), with standard deviation of 0.334 and p (sig) <0.001, and linear progressive manner, as seen above.
Four situations were created to carry out inter-observer variation measurements between the nine doctors who rated the images: prototype evaluation in T1 (S1); CT evaluation in T1 (S2); prototype evaluation in T2 (S3); CT evaluation in T2 (S4). In all situations, the same scenario was found: 9 appraisers and 18 radiographs to be examined, resulting in 162 ratings in each scenario. We obtained alpha coefficients Krippendorff of: 0.227 in S1; 0.161 in S2; 0.152 in S3 and 0.095 in S4. We wish to highlight that this factor varies between 0 and 1, wherein 0 indicates no correlation and 1 the perfect agreement [17]. Thus, it is clear that the four situations do not present a high correlation. However, the correlation expressed in S1 and S3 are larger than in S2 and S4 respectively, which indicates, even if slight, greater inter-observer agreement in the PT compared to the CT.

Regarding the intra-observer variation in PT, 76.13% of the variation in the ratings was due to intra-observer variation, with 30.33% corresponding to 45.8% repeatability and reproducibility. In the CT, 82.69% of the variation was due to the intra-observer variation, with 32.61% corresponding to 50.08% repeatability and reproducibility.

When compared to the averages per anatomical part (PF, FS and KN), we can point out that such average was higher in radiographs of the femoral shaft, which did not obtain any rating less than 4 (Figure 4 – X7, X8, X9, X10, X11 and X12). Moreover, the range of ratings in this group was lower when compared to the marks in the X-rays of the proximal femur and knee in both the PT (Figure 4A) and the CT (Figure 4B).

In order to evaluate the means per evaluators, we can point out that in both the PT (Figure 5A) and the CT (Figure 5B), the ratings offered by radiologists (Figure 5A - RAD1, RAD2 and RAD3) were the highest averages [4.126 in PT (standard deviation of 0.725) and 4.106 in the CT (standard deviation of 0.594)]. The average of the orthopedists’ ratings were 3.93 in the PT (standard deviation of 0.704) and 4.07 in the CT (standard deviation of 0.667) and the average of the resident physicians’ were 4.04 in the PT (standard deviation 0.297) and 3.96 in the CT (standard deviation of 0.045)].
Discussion
The use of TT is still somewhat controversial in the orthopaedic field [18-24]. A study in Brazil showed that about 50% of the orthopaedic surgeons in this country use the table as an aid in the treatment of closed femur fracture [25, 26].

Şahin et al. reported that manual traction compared to the conventional traction table reduced the preparation time and the total duration of anesthesia for osteosynthesis with intramedullary unstable intertrochanteric femoral fractures, however at an increase in the number of surgical aids required [27].

One of the advantages of the use of the TT is the possibility of use in conjunction with the C-Arm. However, Ahmet Firat et al. have demonstrated that the technique with the supine patient position with the contralateral leg elevated facilitates obtaining orthogonal femoral fluoroscopy with the bow, and a reasonable treatment option for the synthesis with femoral intramedullary nail [28].

Lovisetti and Bettella [29] mentioned the use of traction table to help in the reduction and support of tibial fractures and the assembly of the Ilizarov circular external fixator. Similarly, in the Orthopaedics service of the Federal University of Ceará (UFC), a portable traction table has already been used for the assembly of the Ilizarov apparatus and to assist in the positioning for osteosynthesis of some knee fractures, like tibial plateau fractures.

The said portable table was used only for this type of assembly because its joint use with the C-Arm was neither practical nor provided quality images acceptable for other surgical procedures, especially of the femur. The poor quality was mainly due to the presence of many artifacts on radiographs, particularly in lateral incidence.

After disclosure of the technique of Ahmet Firat et al. [28], in which the simple lifting of the contralateral leg, similar to the cross-table lateral radiograph [30, 31], allowed an alternative to the difficulty in obtaining a quality radiograph on the portable table already used. This technique enabled for the use of the PT in other procedures (Figure 6).

The PT consists of a model of a portable table for the orthopaedic traction of the lower limbs, made of stainless steel, with a macrometer proximal telescoped and interchangeable type for the lower right and left limb, with radiolucent perineal post coupled to the telescoped system. Distal foot-support, with height and rotation adjustment, inte-
integrated to the micrometer traction through a threaded rod (Figure 1 and Figure 7).

Due to its lighter weight and smaller size compared to the CT and to the material used in the prototype (basically tubular stainless steel and plastic), the cost of such a device has become quite affordable. A very important feature, since in many countries the economic outlook is of scarce resources, including the health sector. The incorporation of new technologies and alternatives of lower costs but good quality is essential to the implementation of favorable cost-effective assistance, especially of a medicine that is appropriate to patients [32].

When comparing the quality of the radiographic images obtained with the PT and the CT, very similar values were observed, with the averages of the ratings slightly higher for the CT (Table 1).

Both models showed low inter-observer agreement, similar to that found in some ultrasound examinations of the abdomen and breast [33]. However, the intra-observer agreement was good with a slight advantage of the PT, which leads us to inferring that both tables provide very similar images in regard to quality.

It was observed that the average ratings of the orthopedists and medical residents were lower than those of the radiologists. This can be explained by the fact that orthopaedic surgeons and residents assess image quality thinking of possible surgical procedures that can be performed with such X-ray. Moreover, we again emphasize the similarity of the two tables, as seen in Figure 4, especially when shaft femur radiographs are compared.

Following such considerations, we conclude that the radiographic images obtained with the aid of the PT are of similar quality compared to those obtained with the aid of the CT. Now, further studies can be carried out to verify the efficacy of the prototype device in terms of applying traction to a patient for surgery.

Ethical standards
The study complies with the 1964 Helsinki Declaration and its later amendments. The study was approved by the local Research Ethics Committee (CAAE: 53481216.8.0000.5049 - Brazil), and all patients provided informed consent before being enrolled.

Conflict of interest
The authors declare that they have no conflict of interest.

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