

STUDY ON IMPLANT STABILITY IN CEMENTLESS TOTAL KNEE ARTHROPLASTY

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ABSTRACT

Objetives: Determine the stability of tibial and femoral components of 20 cementless knee arthroplasties with rotating platform. **Methods:** The 20 patients (20 knees) underwent an analysis of dynamic radiographs with an image amplifier and maneuvers of varus and valgus which were compared to static frontal and lateral radiographs of the knees and analyzed by two experienced surgeons in a double-blind way. **Results:** We could observe in this study that both

methods showed very similar results for the stability of the tibial and femoral components ($p < 0.001$) using the Kappa method for comparison. **Conclusion:** The tibial component was more unstable in relation to the femoral component in both static and dynamic studies. **Level of Evidence IV, Case Series.**

Keywords: Knee arthroplasty. Knee prosthesis. Knee osteoarthritis. Biomechanics.

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INTRODUCTION

Total knee arthroplasty (TKA) is one of the more effective, reliable procedures with reproducible results in orthopedic surgery. It presents exceptional results in pain relief and functional restoration in patients with inflammatory arthritis and osteoarthritis, with low rates of aseptic loosening at 10 years.¹⁻³

Nowadays, the gold standard in knee arthroplasty is the use of metallic components cemented into the femur and tibia.⁴⁻⁹ However, countless surveys have been carried out in an attempt for us to increase the quality of component fixation in the bone and to reduce the long-term loosening rate.

One of the causes of early loosening of TKA components is the fixed tibial baseplate, where the polyethylene is rigidly secured to the component, disallowing movement. This rigid fixation leads to greater friction between and among the arthroplasty components, producing greater wear and tear on the polyethylene and the release of debris, which contributes to the aseptic loosening of the implant. A tibial component with rotating platform was created in an attempt to minimize this friction on the implant-bone interface, where the polyethylene can move rotationally on the tibial component, thus reducing the friction.¹⁰⁻¹² Another alteration introduced over the years was the

substitution of cemented component fixation by cementless arthroplasty. Cementless TKA was initially idealized for young individuals, in the hope of reducing bone loss during the reviews that would take place in the future, and of reducing the surgical time and the systemic complications of cementation. For this purpose implants were created with rough surfaces of hydroxyapatite, which would theoretically stimulate bone growth and implant osteointegration, increasing the duration of the effects of surgery.¹³⁻¹⁵

Cementless knee arthroplasties have been in use for more than 20 years with good outcomes in our field.¹⁶ However, articles are still controversial in relation to the results of this technique, when compared with cemented arthroplasties.^{11,12,17-20} The main problem pointed out by critics of the cementless technique is early tibial loosening. The main parameter for evaluating the loosening of arthroplasty components is the presence of radiolucent lines in postoperative radiographs, situated on the fringes of the components. Radiolucent lines can be present right from the immediate postoperative period and will only become a concern to the surgeon when their pattern changes over the course of the follow-up period, which can mean the loosening of the components and the need to review the arthroplasty.²¹

All the authors declare that there is no potential conflict of interest referring to this article.

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There are numerous parameters of evaluation and quantification of radiolucent lines and of the loosening of the arthroplasty components. The parameter most commonly used today is the classification of the American Knee Society based on anterior and lateral knee radiographs,²² where radiolucent lines are quantified according to their location around the tibial and femoral components. This evaluation is usually carried out by experienced surgeons who determine whether the components are stable or unstable. Another method for evaluating component stability is the use of dynamic images with an image intensifier (radioscopy). This method involves the performance of knee maneuvers with varus and valgus stress, which are simultaneously documented by the image intensifier, with the ability to determine the movement of the components and its stability.²³

Due to the reduced number of studies conducted in the investigation of cementless knee arthroplasty stability and in the comparison of evaluation methods, we carried out this study to compare two femoral and tibial component stability evaluation methods in cementless total knee arthroplasty with rotating platform.

MATERIALS AND METHODS

We evaluated 20 cementless arthroplasties (20 patients) with rotating platform with at least one year of follow-up. The patients were operated in 2007 and 2008, averaging 17.6 months of postoperative time (12-31 months), being chosen at random for performance of the cementless arthroplasty. The patients' average age was 62 years (ranging between 52 and 75 years) at the time of surgery, with 16 women and four men. All the patients were informed of the surgical procedure and signed a consent form to take part in the study.

All the operations were performed using a medial parapatellar approach, sacrificing the posterior cruciate ligament. The bone cuts were made with standard guides and the surgeons used cementless total knee arthroplasty with a New Wave rotating platform from the Lepine group.

The femoral and tibial components were of chromium-cobalt-molybdenum with porous coating of 120 micrometers. The patellar component was fixed directly on the patella through cementation and two fixator pins. Vacuum drainage was used in all the cases, and was removed when the debit was below 100ml at 24 hours and in the other cases, at 48 hours.

The patients were discharged on the fourth postoperative day allowing partial weight bearing with walking frame. Weight bearing was progressively increased, making the transition to a contralateral cane at three to four weeks and to total weight bearing at six to eight weeks.

The patients were assessed at 1, 3, 6 and 12 and 24 weeks. After this initial phase, the patients made a return outpatient visit every six months up to two years after the surgery and annually after this date.

In the first stage of the study radiographs were taken of the operated knee in orthostatic frontal view with monopodal support and in absolute lateral view of the knee with 30 degrees of flexion in each patient. The images were analyzed, on different occasions, by two surgeons with experience in knee arthroplasty, to check the pattern of the radiolucent lines in the femur and in the tibia, verifying whether the femoral and

tibial components were stable or unstable, analyzing each component separately. The responses were noted down in different places for each surgeon (double-blind procedure).

The second phase of the study consisted of the dynamic analysis of the femoral and tibial components, recording real-time images with an image intensifier, when we performed varus and valgus stress maneuvers on the operated knees.

The patients were positioned in dorsal decubitus on the radiography table and an initial static image of the knee operated in extension was documented. After the image was captured and photographed, we performed a varus and valgus stress maneuver of the knee in extension, where both images were documented and analyzed in real time. At this time we were able to analyze whether one of the components, which appeared stable in the static image, would present instability in the dynamic examination.

The images of the static and dynamic examinations were documented and kept for subsequent comparison with the radiographic examination.

For the statistical analysis of results and for the evaluation of the agreement of results between the different examiners and the radioscopy, we used the Kappa test at a significance level of 5%, which evaluates the concordance between responses. The tested hypothesis is whether the Kappa index is equal to 0, which would indicate null concordance, or if higher than zero, which means concordance is greater than chance. Upon finding a p-value <0.05, this indicates that the measure of concordance is significantly greater than zero, which would indicate the existence of some concordance. This does not necessarily mean that the concordance is high.

To supplement the analysis we observe the Kappa index that points out the degree of concordance: the closer to 0 the higher the concordance and the closer to 1, the better the concordance. Thus the maximum value of the Kappa measure is 1 (total concordance) and values close to or below 0 (indicating no concordance).

The interpretation of the concordance values followed the methodology proposed by Landis and Koch.²⁴ (Table 1)

RESULTS

The results of the static and dynamic analysis by the specialists and of the radioscopy, respectively, were compared separately for the tibia and femur, for us to test two methods for analysis of the stability of cementless knee arthroplasties. (Table 2)

The absolute frequencies (n) and relative frequencies (%) were presented for the qualitative variables. The mean and median and standard deviation, minimum and maximum were used as summary measures to indicate variability for the quantitative variables. (Tables 3 to 8)

Table 1. Table of concordance of the Kappa method.

| Kappa Values | Interpretation |
|--------------|----------------------------|
| <0 | No concordance |
| 0-0.19 | Poor concordance |
| 0.20-0.39 | Slight concordance |
| 0.40-0.59 | Moderate concordance |
| 0.60-0.79 | Strong concordance |
| 0.80-1.00 | Almost perfect concordance |

Table 2. Final comparative analysis of the results of the examiners and of the radioscapy.

| Patients | Examiner 1 | | Examiner 2 | | Radioscapy | |
|----------|------------|--------|------------|--------|------------|--------|
| | Tibia | Femur | Tibia | Femur | Tibia | Femur |
| 1 | Stable | Stable | Stable | Stable | Stable | Stable |
| 2 | Stable | Stable | Stable | Stable | Stable | Stable |
| 3 | Stable | Stable | Stable | Stable | Stable | Stable |
| 4 | Stable | Stable | Stable | Stable | Stable | Stable |
| 5 | Stable | Stable | Stable | Stable | Stable | Stable |
| 6 | Stable | Stable | Stable | Stable | Stable | Stable |
| 7 | Stable | Stable | Stable | Stable | Stable | Stable |
| 8 | Stable | Stable | Stable | Stable | Stable | Stable |
| 9 | Stable | Stable | Stable | Stable | Stable | Stable |
| 10 | Stable | Stable | Unstable | Stable | Stable | Stable |
| 11 | Unstable | Stable | Unstable | Stable | Unstable | Stable |
| 12 | Stable | Stable | Stable | Stable | Stable | Stable |
| 13 | Stable | Stable | Stable | Stable | Stable | Stable |
| 14 | Stable | Stable | Stable | Stable | Stable | Stable |
| 15 | Stable | Stable | Stable | Stable | Stable | Stable |
| 16 | Unstable | Stable | Unstable | Stable | Unstable | Stable |
| 17 | Stable | Stable | Stable | Stable | Stable | Stable |
| 18 | Stable | Stable | Stable | Stable | Stable | Stable |
| 19 | Unstable | Stable | Unstable | Stable | Unstable | Stable |
| 20 | Stable | Stable | Stable | Stable | Stable | Stable |

Table 3. Result of the tibial evaluation by examiner 1.

| Tibia - Examiner 1 | | |
|--------------------|----|-----|
| | n | % |
| Unstable | 3 | 15 |
| Stable | 17 | 85 |
| Total | 20 | 100 |

Table 4. Result of the femoral evaluation by examiner 1.

| Femur - Examiner 1 | | |
|--------------------|----|-----|
| | n | % |
| Stable | 20 | 100 |

Table 5. Result of the tibial evaluation by examiner 2.

| Tibia - Examiner 2 | | |
|--------------------|----|-----|
| | n | % |
| Unstable | 4 | 20 |
| Stable | 16 | 80 |
| Total | 20 | 100 |

Table 6. Result of the femoral evaluation by examiner 2.

| Femur - Examiner 2 | | |
|--------------------|----|-----|
| | n | % |
| Stable | 20 | 100 |

Table 7. Result of the dynamic evaluation of the tibia by radioscapy.

| Tibia (Radioscapy) | | |
|--------------------|----|-----|
| | n | % |
| Unstable | 3 | 15 |
| Stable | 17 | 85 |
| Total | 20 | 100 |

Table 8. Result of the dynamic evaluation of the femur by radioscapy.

| Femur (Radioscapy) | | |
|--------------------|----|-----|
| | n | % |
| Stable | 20 | 100 |

Comparison of results for the tibia

To compare the results obtained by the first examiner in relation to the radioscapy, note that there is perfect concordance ($p < 0.05$) between the two results, i.e., the result was identical ($\kappa = 1$). (Table 9)

To compare the results obtained by the second surgeon in relation to the radioscapy, note that there is almost perfect concordance ($p < 0.05$) between the two results, presenting a Kappa equal to 0.828. (Table 10)

After this there was a comparison of the results obtained by the two surgeons. Based on the results it can be seen that there is almost perfect concordance ($p < 0.05$) between the two results, presenting a Kappa equal to 0.828. (Table 11) and (Figures 1-3)

Comparison of results for the femur

The results obtained by the two surgeons and by the radioscapy were stable for all the patients, indicating 100% of concordance of results. In this case (total concordance) we do not calculate the Kappa value.

Table 9. Comparative analysis of the tibia by examiner 1 and radioscapy.

| | | | Tibia (Radioscapy) | | Total |
|--------------|----------|--------|--------------------|--------|---------|
| | | | Unstable | Stable | |
| Tibia (Ex.1) | Unstable | n | 3 | | 3 |
| | | % | 15.00% | | 15.00% |
| | Stable | n | | 17 | 17 |
| | | % | | 85.00% | 85.00% |
| Total | n | 3 | 17 | | 20 |
| | % | 15.00% | 85.00% | | 100.00% |

Tibia (Examiner 1) * Tibia (Radioscapy) - Kappa = 1.0 - p-value < 0.001.

Table 10. Comparative analysis of the tibia by examiner 2 and radioscapy.

| | | | Tibia Radioscapy | | Total |
|--------------|----------|---|------------------|--------|---------|
| | | | Unstable | Stable | |
| Tibia (Ex.2) | Unstable | n | 3 | 1 | 4 |
| | | % | 15.00% | 5.00% | 20.00% |
| | Stable | n | | 16 | 16 |
| | | % | | 80.00% | 80.00% |
| | Total | n | 3 | 17 | 20 |
| | | % | 15.00% | 85.00% | 100.00% |

Tibia (Examiner 2) * Tibia (Radioscapy) - Kappa = 0.828 - p-value < 0.001.

Table 11. Comparative analysis of the tibia by examiner 1 and examiner 2.

| | | | Tibia (Ex.1) | | Total |
|--------------|----------|--------|--------------|---------|--------|
| | | | Unstable | Stable | |
| Tibia (Ex.2) | Unstable | n | 3 | 1 | 4 |
| | | % | 15.00% | 5.00% | 20.00% |
| | Stable | n | | 16 | 16 |
| % | | | 80.00% | 80.00% | |
| Total | n | 3 | 17 | 20 | |
| | % | 15.00% | 85.00% | 100.00% | |

Tibia (Examiner 2) * Tibia (Examiner 1) - Kappa = 0.828 - p-value < 0.001.

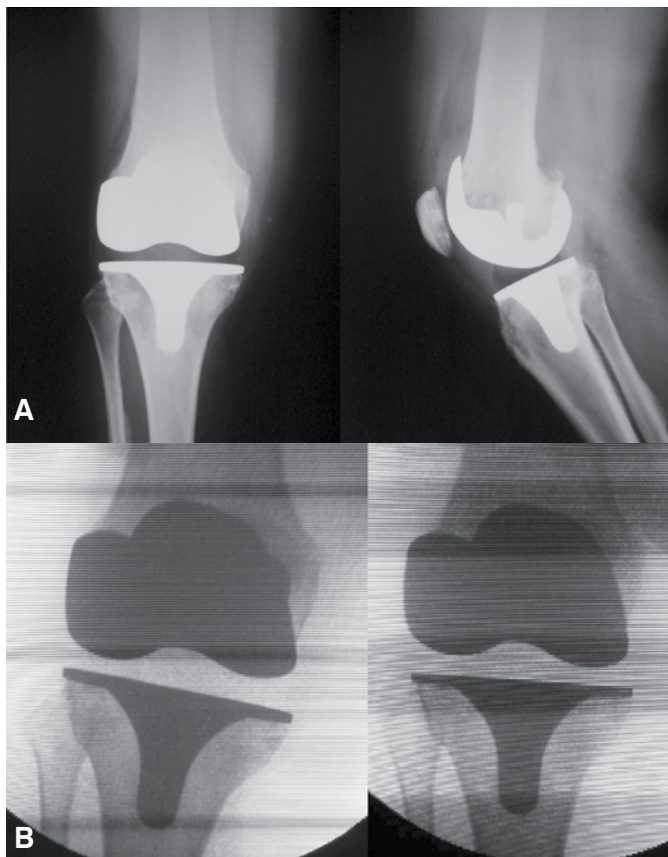


Figure 1. Static evaluation (radiography – A) and dynamic evaluation (radioscopy – B) of patient 7. Note that there are no signs of radiolucency or lysis in the components in the static analysis and that there is no movement of the components in the dynamic analysis.

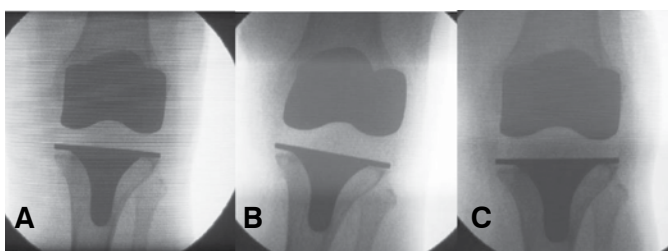


Figure 2. Dynamic evaluation (radioscopy) in neutral (A), varus (B) and valgus (C) of patient 11. Note radiolucent lines in the medial plateau in the static radioscopy. Note appearance of lateral radiolucency in the tibial component in the varus stress maneuver.

DISCUSSION

Beaupré et al.²⁵ presented a comparative study between cemented and cementless knee prostheses evaluating clinical aspects and did not find any difference between the two groups. Most authors consider that the absence of pain after the use of cementless prostheses consists of the clinical method for evaluating implant integration. In this study, besides the clinical evaluation, we opted to add methodology with dynamic and static radiographic examination in the implant analysis. In our study the methodology executed to evaluate implant stability presented good inter-observer correlation. The comparative analysis of the femoral components between the two

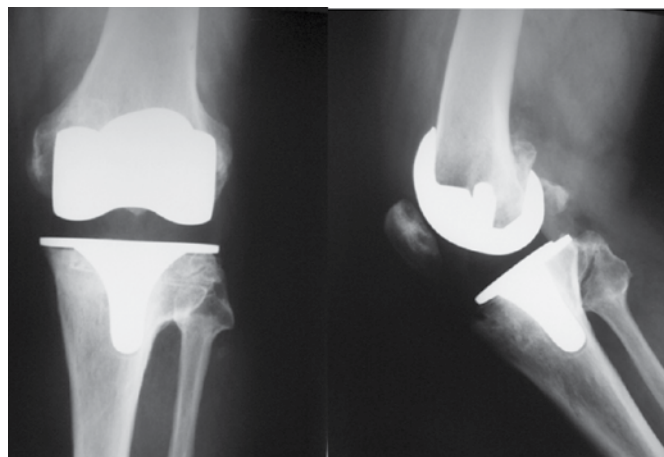


Figure 3. Radiography of patient 16 showing signs of radiolucency in the medial and lateral plateau and around the centralization nail of the tibial component.

examiners and the radioscopy presented concordance in all the cases with a Kappa index of 1.

After analyzing the comparative data between the static and dynamic techniques for evaluating stability of the tibial and femoral components in cementless knee arthroplasty with rotating platform, we can conclude that the two methods produce similar results in terms of stability of the components. This was demonstrated by the positive statistical correlation ($p < 0.001$) in the comparison between the two methods.

Hildebrand et al.²⁶ conducted a study analyzing the migration of cementless implants and demonstrated that there is some degree of migration of the components until implant osteointegration occurs. Regner et al.²⁷ demonstrated that cemented implants migrate less initially, yet constantly over a five-year period, and that cemented implants only migrate in the first six months. This may be due to osteointegration of the implant. The presence of radiolucency around the cementless implant does not necessarily mean the loosening of the component, but may result from its initial migration. In our study three patients exhibited signs of radiolucency around the implant, but did not present movement of the implants in the analysis performed or any other signs of loosening. These patients will be followed up for a longer period of time with the intention of observing the evolution of the radiolucent lines.

When we compare the stability of the femoral components from the present study with the data presented in literature, we can conclude that the pattern of stability of the components followed most studies, demonstrating that cementless total knee arthroplasties with rotating platform can show signs of instability in the tibial component, while the femoral component is stable in the majority of cases.

Going from the methodology applied, we can claim that static radiographic analysis performed by experienced surgeons and dynamic analysis through radioscopy produce similar results in the evaluation of the stability of tibial and femoral components in cementless total knee arthroplasties with rotating platform. This result leads us to believe that the cementless arthroplasties evaluated present osteointegration.

We consider that the current generation of cementless implants

is different to that presented in the past. The first generation of cementless knee prostheses presented poor and discouraging results. This is possibly due to the inappropriate design of the implants and other factors such as the presence of metalback in the patellar component and the use of polyethylene that may have increased debris production.²⁸ The current generation of cementless implants presents positive results in relation to osteointegration, and it is worthwhile conducting further studies on this line of arthroplasties that may be a trend in knee prostheses as has been observed historically in hip prostheses. As a study limitation, we considered the non-inclusion in this analysis of other methods for evaluating the stability of tibial and femoral components, such as bone scintigraphy, and we did

not define the gold standard in the evaluation of the stability of components in a knee arthroplasty. The study conducted out here is not intended to provide a comparative analysis between the functional or durability result of cementless knee prostheses and cemented knee prostheses. Further studies are necessary for better definition of these standards.

CONCLUSION

Based on this study, we can conclude that the static method of evaluation of the stability of cementless knee arthroplasties by experienced surgeons is just as effective as the dynamic evaluation by radiology, whereas both can be used with accuracy in evaluating patients.

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