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The surgeon plays an important role in size planning with patient specific instrumentation for total knee replacement.

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Abstract

Component position and sizing in total knee replacement (TKR) could be improved by patient specific instrumentation (PSI). The purpose of the study was to evaluate the reliability of the manufacturer plan in predicting final component sizes for TKR.

Forty-five TKRs were prospectively enrolled and data on component size were recorded from the initial manufacturer's proposal, the final plan modified after surgeon's and from the actually implanted prostheses.

Pre-operative modifications were required in more than 50% of the cases, with the tibial tray size requiring more frequent changes. The surgeon's planning showed a significantly higher accuracy than the manufacturer's one regarding tibial tray size ($p < 0.05$) but not femoral components size (p: n.s.). Careful evaluation by an experienced knee surgeon is recommended when planning TKR with PSI.

1 Introduction

Better prosthetic component position and accuracy in size choice are among the advantages claimed for patient specific instrumentation (PSI) for total knee replacement (TKR) [1–3]. However,

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only few studies have investigated the reliability of the default plan created by the manufacturers, with some authors advising for care when evaluating these suggestions [4–6]. The purpose of the study was to evaluate the reliability of the manufacturer's plan and the impact of surgeon's changes on the final accuracy of the cutting guide sizes.

2 Materials and methods

The purpose of this study was to compare the proportion of appropriate planning (with respect to the actually implanted size) between the manufacturer's suggestion and the surgeon's final planning.

Morphometric data and a lower-limb computed tomography scan of forty-five consecutive patients were submitted to the PSI manufacturer for instruments design and production and a default pre-operative plan was generated. The surgeon could either accept or modify the proposed size of the implant components.

A cemented prosthesis with patellar resurfacing was implanted using the same sequence of soft-tissue release. PSI cutting guides (Trumatch, DePuy) were used to perform proximal femur and distal tibial cuts. Surgical technique, anesthetic and pain-control medications, antithrombotic and antibiotic prophylaxes and rehabilitation procedures were standardized according to the institution's internal protocols. Prior to completing final femoral and tibial preparation, the implant sizes were checked with conventional instrumentation and the appropriate size was noted and implanted.

Statistical analysis was performed using GraphPad Prism v 6.0 software (GraphPad Software Inc.). The differences for categorical variables were tested using with the Fisher's exact test. For all analyses, the significance level was set at p-value lower than 0.05.

3 Results

Pre-operative modifications were required in more than 50% of the forty-five study patients. The tibial tray size required some pre-operative surgeon's modifications more frequently than the femoral component.

Further intra-operative modifications were needed in 16 patients. The final implant differed from the manufacturer's initial patient proposal in one fifth of the femoral components and half of the tibial trays. The comparison of the accuracy of the manufacturer's initial patient proposal against that revised by the surgeon showed a significantly higher accuracy of the latter regarding tibial tray size ($p < 0.05$) but not femoral components size (p: n.s.).

4 Discussion

This study showed that the surgeon's accuracy to predict the final component size is significantly different from that of the manufacturer, especially for the tibial tray. Sizes changes from pre-operative plan were reported also by Stronach et al. (53% for tibial components and 77% for femoral ones [4]) and Pietsch et al. [5]. The latter also observed a significant superiority of the surgeon's plan to the manufacturer's one. Better sizing accuracy of PSI guides were reported by other authors [1,6–14].

Woolson et al., investigating the same PSI device as the present study (Trumatch, DePuy) reported incorrect pre-operative femoral sizes in 14% of the cases and incorrect pre-operative tibial sizes in

18%[14]. With the same technology Briffa et al. and Chotanaphuti et al. reported lower figures for incorrect pre-operative plan, respectively 5% and 10% for femoral and tibial sizes [11,12].

Limitations in this study are the absence of a control group and the absence of surgeon blinding to the planning during surgery. The fact that the planning and operating surgeon were the same could represent a bias on the choice of the final implant size but nevertheless reduces variability in implant sizing strategies. Moreover, the Authors acknowledge that implant size may also be affected by surgical variables uncontrollable by a planning software, such as patellar issues or ligamentous balancing.

5 Conclusions

Intra-operative modifications to obtain appropriate component size are frequently required when using PSI. Evaluation of the manufacturer's pre-operative planning by an experienced surgeon is of critical importance, since deviations between the suggested and appropriate component size may occur. Blind acceptance of manufacturer's plans is discouraged.

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