



Does the Kinematch[®] Prosthesis Impair Knee Flexion in Patients with Trochlear Dysplasia?

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Abstract

Background: Patellofemoral replacements are used to treat isolated patellofemoral arthritis in carefully selected patients. The Kinematch[®] custom-designed implant is placed directly on subchondral bone, leading critics of the device to believe that this results in overstuffing and limitation of flexion in cases of trochlear dysplasia; the current study aims to evaluate this premise.

Methods: A retrospective analysis of a consecutive series of 24 patients (32 knees) was conducted. Trochlear dysplasia was evaluated using pre-operative axial CT scans, and knees were categorized as having minimal or moderate/severe dysplasia (moderate = flat trochlea, severe = convex trochlea). The primary outcome was post-operative knee flexion.

Results: There was no statistical or clinical difference in post-operative knee flexion between the minimal ($120^{\circ}+12$) and the moderate/severe dysplasia ($117^{\circ}+9$) groups ($p=.34$).

Conclusions: Use of the Kinematch[®] patient-specific custom trochlear component does not significantly limit flexion in cases of trochlear dysplasia, and although the surgeon has the ability to deepen the trochlea by way of the pre-operative model, this is not necessary.

Keywords: Patellofemoral replacement; custom; flexion; trochlear dysplasia

Level of Evidence: III, Case-control study

Introduction

Patellofemoral replacements are available in a number of formats: inlay, onlay, off-the-shelf, custom and combinations thereof. One implant, Kinematch[®] (Kinamed[®], Camarilla, CA), features a custom trochlear component that is modeled on three-dimensional CT reconstructions to match the subchondral bone of the trochlea (Figure 1). No bone is removed from the trochlea unless the surgeon has chosen to do so prior to the creation of the implant. Sisto and Sarin [1] have reported promising results with no revi-

sions at six years. However, some critics of the custom-designed implant believe that the anteriorization of the troch-



Figure 1. A: Model of trochlea with custom-fit prosthesis with patient specific drill guide and marking template. B: Patient specific component and native bone model showing a precise fit.

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lea results in overstuffing of the anterior compartment, leading to increased pain and limited flexion. [2]

It is widely agreed upon in the literature that appropriate patient selection is critical to the success of a patellofemoral replacement. [3,4,5] One of the principal indications for a patellofemoral replacement (PFR) is patellofemoral arthritis secondary to dysplasia [6,7] where, by definition, the trochlea is deficient and/or misshapen. In such cases, will a custom implant limit knee flexion due to overstuffing of the patellofemoral compartment? This is the first study to evaluate post-operative flexion in patients with either normal or dysplastic trochlear architecture receiving this custom-fit PFR.

Methods

PATIENT SELECTION

The study retrospectively assessed a consecutive series of 25 patients (17 unilateral, eight bilateral) who underwent a PFR between 2007 and 2012. All patients received the custom-fit Kinematch® trochlear prosthesis with a standard round all-poly 3-pegged patellar button.

One patient was excluded from the study due to the post-operative diagnosis of subcutaneous malignancy leading to further surgery, resulting in a final study of 24 patients (16 unilateral, eight bilateral). Bilateral procedures were assessed independently of each other for a total of 32 knees. Out of the 32 knees assessed, 21 (66%) were female. The average age at the time of the surgery was 61.1 years (range 44-88 years), and average time to the most recent follow up evaluation was 21.6 months (range 12.5 - 46 months).

MEASUREMENT OF TROCHLEAR DYSPLASIA

Knees were subdivided into groups based on the degree of femoral trochlear dysplasia evaluated according to Dejour & Saggin's criteria [8] and validated by Lippacher et al. [9] (Table 1). First, a "two-grade" analysis of knees was conducted using pre-operative axial CT scans of patient knees. Briefly, knees were categorized as having either minimal dysplasia (Dejour grade A dysplasia; n=17) or moderate/severe dysplasia (Dejour grades B, C, or D dysplasia; n=15). Female patients made up a significantly higher percentage of the moderate/severe dysplasia group (87%) than the minimal dysplasia group (47%), $p = .02$. There was no difference in mean age or time to follow up between the groups (Table 2).

Knees were subsequently classified on a "three-grade" scale in which the moderate/severe dysplasia group from the previous analysis was broken into two groups: flat

trochlea (Grade B dysplasia, n=7) and convex trochlea (Grade C/D dysplasia, n=8). The minimal dysplasia group remained the same. Again, female patients made up a significantly higher percentage of the flat trochlea (71%) and convex trochlea groups (100%) than the minimal dysplasia group (47%), $p = .03$. There was no difference in mean age or time to follow up between the groups (table 3).

OUTCOMES

The primary outcome measure was post-operative knee flexion measured by the surgeon at each post-operative visit (by way of a protractor). Measurements from the most recent follow up visit were used for the study.

ETHICS

The study was approved by the Institutional Review Board of the Mount Sinai School of Medicine.

STATISTICAL METHODS

Statistical analyses were conducted using SPSS version 20 (IBM 2011). Normally distributed continuous variables are presented as mean +/- standard deviation, while nominal data is shown as percentages. Student t-tests were used to compare means of groups in the 2-grade analysis; one-way ANOVAs were calculated to compare means of groups in the 3-grade analysis; similarly, nominal data in both the 2-grade and 3-grade analysis were evaluated via Pearson chi-squared analyses. A stepwise linear regression was performed to determine the interaction of all variables in the database on the prediction of knee flexion. $P < .05$ was considered statistically significant.

Results

"TWO-GRADE" ANALYSIS

The average post-operative flexion in the "minimal dysplasia" (A) group was 120° while the average flexion in the "moderate/severe dysplasia" (B and C-D) was 117°; this is not a significant difference ($p = .34$) (Table 2). Linear regression demonstrated that age, female sex, and time to follow up were not independent predictors of post-operative flexion.

"THREE-GRADE" ANALYSIS OF KNEES

When the dysplastic group was further divided into the moderate (B) and severe (C-D) subdivisions a small, a non-significant difference was noted (120° vs. 115°) (Table 3). Linear regression demonstrated that age, female sex, and time to follow up were not independent predictors of post-operative flexion.

Discussion

There has been a resurgence of interest in PFR surgery as evidenced by the growing number of implants. [10,11] With this increased interest comes the discussion of whether the trochlear groove should be sculpted into a pre-determined shape or left as is.

When the trochlea has a normal shape, the discussion is moot. However, since one of the principal indications for a PFR is arthritis secondary to dysplasia, a significant number of patients receiving a PFR will exhibit an abnormal trochlea. In such cases, if the surgeon does not deepen the trochlea, will flexion be limited?

Kinamed[®] manufactures the Kinematch[®] custom trochlea that offers two main advantages over off-the-shelf inlay prostheses requiring by definition bony cuts and/or milling of the trochlea:

- 1) diminished operative time and
- 2) an intact femur upon revision.

The diminished operative time is the result of the planning and the CT scan performed by the surgeon and the manufacturer pre-operatively. The intact femur upon revision results from no bone having been removed from the trochlea.

The limitation of flexion relates to the issue of “overstuffing” in total knee replacement surgery, except that in cases of trochlear dysplasia, it is the trochlea that is “thick” rather than the patella. Some studies have specifically listed this as a cause of failure in PFR surgeries. [12] However, it has been our suspicion that over-stuffing is not a factor in the custom-designed implant:

- 1) Even in total knee arthroplasty, the concept of overstuffing has now been challenged. [13] Indeed, a few extra millimeters of extra patellofemoral compartment thickness have not been found to significantly limit flexion, the compliance of the peri-patellar soft tissues being a more important parameter.

- 2) A lateral release most likely offsets increases in patellofemoral pressure that might be caused by an increased thickness of the patellofemoral compartment. (We routinely perform a partial lateral release up to but not including the geniculates.)

- 3) There are two surfaces to the trochlear implant: the one touching the trochlea (the “trochlear” surface) and the one facing the patella (the “patellar” surface). The topography of the “trochlear” surface will vary from patient to patient (size, shape and relief), but the patellar surface of the implant is always concave and always matches the patellar button.

- 4) Most significantly, trochlear dysplasia is by and large a condition affecting the proximal trochlea [14], and it is

the distal trochlea that is in play during knee flexion.

In this study group, half the patients had a normal – or only slightly dysplastic- trochlea (DeJour A), while the other half exhibited dysplasia (B and C-D). The dysplasia group was also roughly equally divided between the flat trochleas (B) and the convex trochleas (C-D). Pre-operative and post-operative radiographic images of a patient with severe dysplasia are displayed in figure 2.

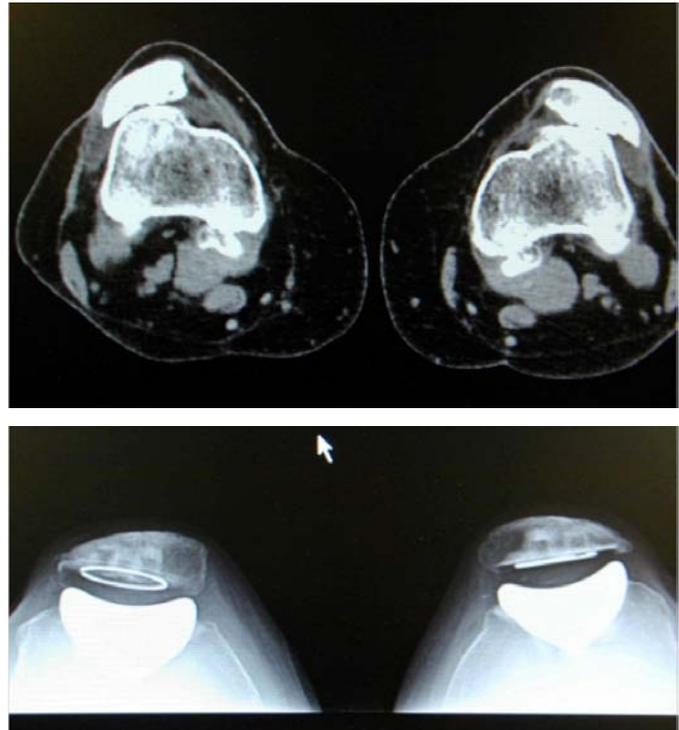


Figure 2. Radiographic imaging of severely dysplastic trochlea (A) pre-operative and (B) post-operative.

Incidentally, the dysplasia was always more impressive on the MRI than on both the plaster model and the prepared trochlear bed, as the cartilage contributes to the size of the prominence (when cartilage is still present).

The surgeon can eliminate the dysplasia pre-operatively by sculpting the plaster model to his/her specifications. The manufacturer will create an implant that matches this re-designed trochlea. (The surgeon then re-creates his sculpting intra-operatively). As this study suggests, these extra steps are not necessary.

A limitation of our study was the application of a protractor to the patients’ leg to assess knee flexion. Application of the protractor to a perfect lateral radiograph would have been better and use of digital computation better yet. Obtaining x-rays for the purpose of measuring flexion, however, is not realistic. Fortunately, the variation in measurements from visit to visit was negligible, suggesting precision if not accuracy. As a measure of reference, the same investigator using the same measuring technique has found an average of 110° of flexion using the DePuy

LCS total knee replacement system (unpublished data). A more generous assessor might have found greater flexion for both the total knee replacements and the patellofemoral replacements.

The time from surgery to final measurement varied from patient to patient, and certainly some of the subjects measured soon after surgery might have continued to see increases in flexion. However, in our experience, a feature particular to patellofemoral replacements (and in contrast to total knee replacements) is the rapid progression to final flexion. Therefore the timing of our measurements relative to surgery was probably of little import.

While two years is a common follow-up minimum for studies relating to joint replacements, this would not seem to apply here as we are not looking at pain, function, wear, or loosening. Likewise, while imaging studies are routinely analyzed and published after joint replacement studies, imaging analysis does not apply to this study.

Will a prominent trochlea affect the stability of the extensor mechanism after surgery with the Kinematch prosthesis? We do not think so. This trochlear component features a normal groove that allows the patella to be captured as soon as the knee flexes. In fact, deepening the groove might lead to increased laxity of the soft tissue envelope and greater instability. We have not formally studied this.

In short, use of a patient-specific custom trochlear component does not significantly limit flexion in cases of

trochlear dysplasia, and although the surgeon has the ability to deepen the trochlea on a pre-operative model, this is not necessary.

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