Evaluation of a Custom Device for the Treatment of Flexion Contractures after Total Knee Arthroplasty

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Abstract Knee flexion contractures can severely impair function after total knee arthroplasties. We evaluated the use of a custom-molded knee device to treat 47 patients who had knee flexion contractures (mean, 22°; range, 10°–40°) after primary or revision total knee arthroplasties and who had failed conventional therapeutic methods. The device was used for 30 to 45 minutes per session two to three times per day in conjunction with standard physical therapy modalities two to three times per week. Twenty-seven of 29 patients who underwent primary total knee arthroplasty and 13 of 18 patients who underwent revisions achieved full extension after a mean treatment time of 9 weeks (range, 6–16 weeks). Full knee extension was maintained at a minimum followup of 18 months (mean, 24 months; range, 18–36 months). The mean Knee Society knee and functional scores improved from 50 points and 34 points to 91 points and 89 points, respectively. This protocol had comparable rates of improvement in knee extension with less treatment time when compared with other nonoperative treatments reported in the literature.

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The custom knee device may be a useful adjunct to a physical therapy regimen for knee flexion contractures after total knee arthroplasty.

Level of Evidence: Level IV, prognostic study. See Guidelines for Authors for a complete description of levels of evidence.

Introduction

Considerable loss of range of motion of the knee may occur in 1% to 15% of patients who have undergone primary TKAs [12, 17, 18, 23, 31, 34]. Additionally, the frequency of knee stiffness may be even higher in patients who have had revision TKA, especially after treatment of a periprosthetic infection [2, 32]. Fixed flexion deformities after TKA are associated with greater levels of pain, gait abnormalities, difficulty with climbing stairs, and poorer function scores [7, 25, 26], all of which can severely impair a patient's quality of life.

Knee flexion contractures may be caused by one or more of several soft tissue factors, including preoperative loss of motion with adaptive muscle shortening [24]; inadequate soft tissue balancing during the procedure [4, 9, 24]; scar tissue adhesion formation from prior surgeries or infections [4]; pain-induced quadriceps muscle inhibition [21]; hamstring or gastrocnemius muscle tightness [27, 33]; limb length discrepancy, with the TKA limb longer than the unaffected side resulting in knee flexion [31]; or peroneal nerve entrapment resulting in a flexed knee posture to reduce tension on the nerve [13, 22].

A variety of rehabilitation techniques have been used to treat knee flexion contractures. These include moist heat, hamstring and gastrocnemius muscle stretching, extensor mechanism strengthening exercises, and manipulation of

Fig. 1 The customized knee device is composed of polyester casting material, two hinges, and an elastic band.

the joint as well as the soft tissues [6, 20]. Other approaches include neuromuscular electrical stimulation, joint aspiration, corticosteroid and/or local anesthetic injections into the joint, and botulinum toxin injections into the hamstring and gastrocnemius muscles [31]. Various orthoses have also been used, including casts or braces to hold the joint in extension [1]; low-load progressive stretch splints, which apply a constant low-grade force to the joint to gradually extend it [29]; and static progressive stretch splints, which hold the joint at progressively greater degrees of extension [5]. These methods may require prolonged treatment times (e.g., 4 to 55 weeks). In an attempt to create a treatment option that requires fewer rehabilitation visits, one of the senior authors (AB) developed a custom knee device (CKD) composed of polyester casting material, two hinges, and an elastic band (Fig. 1). This device was intended as an adjunct that patients can use at home to supplement their physical therapy treatments.

The purpose of our study was to determine whether the passive ranges of motion and Knee Society scores of patients who had knee flexion contractures after TKA improved after treatment with the CKD. We also statistically compared the results of the patients who had primary and revision total knee arthroplasties.

Materials and Methods

Between July 2003 and June 2007, we treated 47 patients who had flexion contractures with a CKD in conjunction with a standardized physical therapy regimen. Inclusion

criteria consisted of flexion contractures greater than 10° after TKA and at least 4 to 8 weeks of conventional physical therapy with no improvement. We excluded patients who had heterotopic ossification, prosthetic malalignment, oversized components, or other motion-limiting abnormalities of the bone or prosthesis. All patients who met the inclusion and exclusion criteria agreed to begin the CKD treatment and take part in the study. The patients included 18 men and 29 women who had a mean age of 62 years (range, 47–71 years). Twenty-nine of the patients had undergone primary TKA, and 18 patients had undergone revision TKA. These were from a pool of 439 patients who underwent primary TKA and 139 patients who underwent revision TKA during that time. The range of motion before the index TKA or revision arthroplasty had not been consistently recorded, so these could not be reported. We measured the passive knee range of motion once per week during treatment to determine whether improvement was occurring. Additionally, we assessed the Knee Society knee and functional scores [11], and satisfaction ratings of each patient before and after treatment. We compared these values with published studies of other nonoperative treatment methods. The minimum followup time was 18 months (mean, 24 months; range, 18–36 months). The study received full Institutional Review Board approval.

All of the TKAs were performed by one of the senior authors (MAM). The primary TKAs utilized TriathlonTM cruciate-retaining knee systems (Stryker Orthopaedics, Mahwah, NJ). The revisions used TriathlonTM posterior-stabilized or total-stabilized knee systems (Stryker). The revisions had been performed for periprosthetic infection (11 patients), knee stiffness (four patients), and component loosening (three patients).

Postoperatively all patients received inpatient physical therapy twice per day (consisting of active and passive range-of-motion exercises, full weight-bearing gait training, and teaching for home exercises) for the first 3 to 4 postoperative days. Twenty-four patients received additional physical therapy at an inpatient rehabilitation hospital for 7 to 10 days. After discharge to home, 30 patients followed a home physical therapy protocol that consisted of range-of-motion as well as weight-bearing exercises twice per week, and 17 patients received outpatient physical therapy services two to five times per week.

All patients were evaluated in the office approximately 6 ± 2 weeks after their surgeries, where we determined their passive ranges of motion and Knee Society scores. At that time, patients who had passive knee flexion contractures greater than 10° and who met the inclusion/exclusion criteria were referred to the physical therapy office, where a CKD was custom built and the treatment began. Patients who lived a long distance from our institution were referred

to a local physical therapy office for the adjunctive therapeutic treatments. The mean pretreatment passive knee flexion contractures were 22° (range, 10° – 40°) and 24° (range, 20° – 30°) for the patients who had undergone primary and revision TKA, respectively. The pretreatment Knee Society knee and functional scores were 50 points (range, 25–76 points) and 34 points (range, 15–70 points), respectively. Forty-five of the 47 patients began the CKD treatment on the day of the followup visit. The remaining two patients had peroneal nerve entrapment symptoms (pain and numbness radiating to the dorsum of the foot and exacerbated by knee extension as well as mild extensor hallucis longus muscle weakness) in addition to the knee flexion contracture, so they underwent surgical peroneal nerve releases, and then they began the CKD treatment approximately 7 weeks after the TKA.

All of the CKDs were designed using a standardized technique. Polyester-based casting tape (Dynacast PII BSN Medical, Charlotte, NC) was used to make the brace. The patient was placed in a supine position and a stockinette was applied. The knee axis was marked, and one layer of casting tape was applied to the thigh and lower leg (Fig. 2). Polycentric knee hinges were bent around the knee in

Fig. 2 The patient is placed in a supine position, a stockinette is applied, the knee axis is marked, and one layer of polyester casting tape is applied to the thigh as well as the lower leg.

Fig. 3 Polycentric knee hinges (arrow) are bent around the knee in alignment with the axis to conform to the individual anatomy of the patient.

alignment with the axis to conform to the anatomy of the patient (Fig. 3). The remaining layers of the cast were then applied. Once the hinges were incorporated into the cast, two proximal and two distal hooks were applied. These hooks were then used as fulcrums to anchor an elastic band for the application of tension. After the cast was sufficiently dry, it was cut longitudinally and removed. Then the edges were trimmed and lined with adhesive fleece for patient comfort (Fig. 4). Patients were shown how to apply and remove the brace (Fig. 5), and were advised to keep it on only during each stretching session. In some patients, the cast loosened after 4 to 8 weeks and was rewrapped with new casting tape by a physical therapist. Each brace took approximately 60 to 90 minutes to construct for each patient, with a total charge to the patient (including cost of materials and labor) of \$235 to \$275. All braces used in this study were fabricated by one of the authors (AB), but other physical therapists have successfully learned how to build a CKD through an 8-hour course, with 4 hours of hands-on training.

Fig. 4 When the cast is dry, the edges are trimmed and lined with adhesive fleece for patient comfort.

Fig. 5 A patient removes the brace after the completion of a stretching session.

A standardized protocol for use of the CKD was given to all of the patients. We advised them to sit or lie supine and to prop their heels on a pillow at the same height as the hip. Next, they applied an elastic band (Thera-Band; The Hygenic Corporation, Akron, OH) to the hooks in a figure-of-eight configuration, crossing the distal femur to provide knee extension force (Fig. 6). Soft ankle weights (5 to 10 pounds each) were placed on the table immediately adjacent to the lateral ankle, knee, and thigh as a physical block to prevent the leg from rotating externally during treatment. Each stretching session was performed for 30 to 45 minutes two to three times per day. On the days on which physical therapy was performed, the patients were encouraged to apply the CKD for 30 minutes prior to the physical therapy session to relax the soft tissues. Ten of the patients were unable to perform the stretching protocol by themselves, so the patients visited the physical therapy office daily as outpatients, where the device was applied by a physical therapist for 30 minutes, then they underwent an adjunct physical therapy session, then the device was applied again for 30 minutes. The CKD protocol was continued for 2 to 3 weeks after full extension was achieved to maintain the correction. If a patient followed the protocol for a minimum of 6 weeks with no improvement in passive knee flexion contracture or symptoms, then the device was discontinued.

Fig. 6 An elastic band is applied to the hooks in a figure-of-eight configuration, crossing the distal femur to provide knee extension force.

An adjunctive physical therapy protocol was followed concurrently with the CKD treatment. Two to three times per week, each patient underwent a physical therapy regimen that included (1) moist heat; (2) soft tissue mobilization of the posterior aspect of the knee (at the distal hamstring and proximal gastrocnemius muscle insertions) with the patient in a prone position and maximal knee extension; (3) anteroposterior joint mobilization of the femur with the patient in a supine position and the proximal tibia supported by a bolster to promote end-range knee extension; (4) gastrocnemius and hamstring muscle stretching with the patient in a supine position with the heel supported and the knee in maximum extension; (5) neuromuscular electrical stimulation with electrodes applied over the vastus medialis obliquus and proximal vastus lateralis muscles (20- to 30-minute duration, alternating 6 seconds on and 18 seconds off, waveform at 50 to 90 pulses per second, 400- μ sec pulse duration, and maximally tolerated intensity); and (6) weight-bearing exercises, including leg press and end-range knee extension.

We measured various clinical outcome variables during the course of treatment, after the completion of treatment, and annually thereafter. Passive range of motion was measured with a long-arm goniometer by two authors (EB and AB, licensed physical therapists) with the patients lying supine with 10° to 15° of hip flexion. Inter- and intraobserver reliability was examined by having each author measure 10 patients three times each. The inter- and intraobserver measurements were within 3° of each other for extension 100% of the time, and were within 3° of each other for flexion 95% of the time. After the completion of treatment, each patient followed up in the office, where we determined the passive knee range of motion, the Knee Society knee as well as functional scores [11], and the overall treatment duration in weeks. Additionally, each patient rated his or her satisfaction with the CKD treatment using a Likert scale that ranged from zero to 10 points [14], with zero points indicating complete dissatisfaction and 10 points indicating complete satisfaction.

We used a paired Student *t* test to compare the pre-treatment and posttreatment knee flexion contractures and Knee Society scores. We also used a Student *t* test to compare the range of motion, Knee Society scores, and satisfaction scores of the two patient cohorts (primary and revision TKA). All of the data met the assumptions of normality ($p > 0.05$ by the Kolmogorov-Smirnov test with Lilliefors' correction) and equal variance ($p = 1.000$ on the Levene Median test). A Mann-Whitney-Wilcoxon test was used to compare the duration of treatment of the two groups, because the data did not pass the normality test. A chi square test was used to compare the failure rates of the two patient cohorts. All statistical analyses were performed using SigmaStat, version 3.5 (SPSS, Chicago, IL).

Results

At the end of the treatment protocol (mean, 8 weeks; range, 6–16 weeks), 40 of 47 patients improved their flexion contractures compared with the pretreatment values ($p < 0.001$), with a mean residual contracture of 1.4° (range, 0° – 15°). The mean Knee Society knee and function scores improved to 91 points (range, 60 to 100 points) and 90 points (range, 60 to 100 points) ($p < 0.001$).

There were substantial differences between the patients who underwent primary and revision TKA, although the mean Knee Society scores of the two cohorts were similar. Patients who underwent primary TKA had shorter ($p = 0.05$) mean treatment times than did patients who underwent revision TKA (9 weeks, range, 6–15 weeks versus 11 weeks, range, 9–16 weeks, respectively). In the primary TKA group, 27 of 29 patients (93%) achieved full extension (defined as a flexion contracture of less than 5°). In the revision TKA group, 13 of 18 patients achieved full extension, while 15 of 18 patients had a flexion contracture of 10° or less. The patients who achieved complete resolution of the flexion contracture maintained full extension at a final followup time of 18 months (range, 12–24 months). The primary TKA cohort had a greater range of motion ($p < 0.001$) compared with the patients who had undergone revisions. The mean Knee Society knee scores of the primary and revision cohorts were similar ($p = 0.167$) at the final followup, with scores of 92 points (range, 75–100 points) and 90 points (range, 60–100 points), respectively. The mean Knee Society function scores of the primary and revision cohorts were also similar ($p = 0.398$), with scores of 91 points (range, 60–100 points) and 87 points (range, 60–100 points), respectively. The mean satisfaction scores of the primary and revision cohorts were also similar ($p = 0.809$), with scores of 9 points (range, 6–10 points) and 8 points (range, 5–10 points), respectively.

Two patients who had received primary TKAs and who failed the CKD protocol required additional surgical procedures. One patient, a 55-year-old man who had a pretreatment passive knee flexion contracture of 30° , experienced no improvement after 6 weeks with the CKD treatment. A manipulation under anesthesia also failed to improve his flexion contracture, so he ultimately underwent a distal hamstring-lengthening procedure. At a followup visit 2 years after surgery, his passive knee flexion contracture was improved to 10° with Knee Society knee and functional scores of 80 points each. Another patient who had received a primary TKA, a 60-year-old woman who had a passive knee flexion contracture of 20° , also failed to improve after 6 weeks of CKD treatment. She eventually underwent a polyethylene insert change and subsequently achieved a passive arc of motion of 0° to 110° with Knee

Society knee and functional scores of 100 and 95 points, respectively. Five patients who were in the revision TKA cohort failed to achieve full extension after 6 weeks of CKD treatment with passive flexion contractures ranging from 10° to 30° . Three of those patients underwent arthroscopic exploration with scar tissue releases, and at final followup times of 2 to 3 years, all had passive flexion contractures of less than 5° with Knee Society knee scores ranging from 85 to 100 points and Knee Society functional scores ranging from 70 to 90 points. The two remaining patients declined further treatment. Their residual knee flexion contractures measured 10° each after treatment times of 16 and 13 weeks, respectively. Their Knee Society knee scores were 81 and 86 points, respectively, and their Knee Society functional scores were 80 and 90 points, respectively, at followup times of 2 years.

Discussion

The treatment of knee flexion contractures after TKA can be difficult. Standard physical therapy protocols may require long periods of time and may not be sufficient to restore range of motion [28]. Low-load, prolonged stretching techniques with therabands and/or ankle weights have been successfully used for years to treat knee flexion contractures, but in our practice, these treatments appeared to be less well-tolerated by patients than splints when maintaining the joint in a stretched position for an extended period of time. Commercial splints may cost over \$2000, and although some orthopaedic practices are able to make arrangements with companies for lower rates, many patients may have difficulty affording those devices. In an attempt to address these problems, the authors designed a customized knee device that used simple materials, had a low cost, and could be used daily by the patient at home. We then evaluated whether the device could be utilized to achieve full knee extension in patients who had knee flexion contractures after primary and revision TKAs.

There were several limitations of this study. There was no separate cohort of patients who were treated with physical therapy alone for comparison, and the patients who were enrolled in this study might potentially have restored their passive ranges of motion with only standard physical therapy modalities without the brace. Additionally, there was no direct comparison to a commercial brace. The type of endpoint of the contracture (hard or soft) was not consistently documented, so it could not be used to interpret the data, and this could have provided more information about which contractures might have better outcomes with this treatment. Finally, the physical therapist who constructed and applied all of the braces also took

part in measuring the range of motion of the patients, which introduces potential bias, although both therapists who performed the measurements attempted to be as accurate and reliable as possible. Although we had no control group, the experimental protocol did resolve the flexion contractures in 27 of 29 patients who had primary TKAs and 13 of 18 patients who underwent revision TKAs after a mean treatment time of 9 weeks (range, 6–16 weeks), compared with reports of physical therapy alone, which were associated with longer treatment times and/or a greater proportion of patients who failed the treatment [15, 19, 28].

The literature review revealed that other nonoperative treatment methods had comparable or inferior results as well as longer mean treatment times (Table 1). The mean final knee flexion contractures ranged from 0.6° to 3° in published reports, and the mean treatment times ranged from 6 months to 2 years. The success rate (the percentage of patients who had a flexion contracture of 0°–5° at final followup) was 85% in one study and was not described in the other reports. Shoji et al. [28] examined 231 patients who underwent conventional physical therapy techniques daily for 2 to 4 weeks, then two to three times per week for 2 to 4 more weeks after primary TKA. They reported that 35 patients (15%) had knee flexion contractures ranging from 5° to 15° at a mean followup time of 3.8 years (range, 2–9 years). McPherson et al. [19] examined 29 patients who had a mean knee flexion contracture of 11° (range, 5°–30°) after TKA. With standard physical therapy treatments (range of motion treatments, soft tissue manipulation, moist heat), the mean flexion contracture decreased to 5°, 2°, 1°, and 1° at 3, 6, 12, and 24 months postoperatively, respectively. Logerstedt and Sennett [16] described the use of a drop-out cast, which held the knee in extension without the application of elastic bands. The cast was applied by the patient for 6 to 8 hours every night in conjunction with stretching, exercise, and knee mobilization, to treat four patients who had a mean age of 20 years and who had recalcitrant knee flexion contractures after anterior cruciate ligament reconstruction. After a mean of 13 weeks of treatment (range, 11 to 16 weeks), the mean knee extension and flexion improved by 7° each. The final mean knee flexion contracture was 4° (range, 1 to 8°). We found a mean final knee flexion contracture of 1.4° after a mean of 9 weeks of treatment (range, 6–16 weeks) and a 93% success rate for patients who had primary TKA, which was comparable to the results of other published treatments, but with a fewer mean hours of treatment.

Surgical treatments, including manipulation under anesthesia, soft tissue release, and revision TKA, have been successfully used to treat knee flexion contractures after TKA; however, they all have associated risks, including skin damage, tendon injuries, bleeding, and

Table 1. Published results of other nonoperative treatments for knee flexion contractures after TKA

Author	Year	Number of knees	Treatment	Mean duration of treatment (range)	Mean pretreatment flexion contracture in degrees (range)	Mean posttreatment flexion contracture in degrees (range)
Tanzer and Miller [30]	1989	35	Intensive physiotherapy	55 weeks (no range given)	14.6 (range not reported)	2.9 (range not reported)
Shoji et al. [28]	1990	231	Organized physical therapy	4–6 weeks	Not reported	35 patients had posttreatment flexion contractures (range, 5°–15°) at 2 to 9 years followup
McPherson et al. [19]	1994	29	Standard physical therapy	12 months	11 (5–30)	1
Lizaur et al. [15]	1997	83	Standard physical therapy	24 months (12–41)	8.8 (0–45)	0.6 (0–10)
Cheng et al. [8]	2007	323	Intensive physiotherapy	1 year	11 ± 6	3 ± 5
Bonutti et al. [5]	2008	21	Static progressive stretch orthosis	9 weeks (3–27)	15 (3–65)	6 (0–45)
Present study	2009	47	Custom knee device	9 weeks (6–16)	22 (10–40)	1.4 (0–15)

infection, in addition to high costs, and they often do not improve the contracture [3, 4, 10, 12]. The treatment used in the present study resulted in improvements in all patients with no complications or operative risks.

The CKD was associated with improved passive knee range of motion, Knee Society scores, and satisfaction of patients who had knee flexion contractures after TKAs. The current protocol cannot be directly compared with published reports of other protocols due to differences in study designs and patient populations, but it did resolve the flexion contractures of a comparable proportion of patients in a relatively short period of time. The brace differs from other low-load progressive stretch techniques because it is custom-designed for each patient, and it can be applied and removed by most patients without assistance, so it can be used at home. Other surgeons could train their physical therapy staff to construct and utilize these braces at a relatively low cost, although fabrication quality might be variable. The effectiveness and cost of this brace have not been directly compared with other regimens in a randomized controlled trial, so a prospective comparison study is necessary to determine any relative benefits of this technique. In conclusion, this approach offers an alternative regimen that may be incorporated into rehabilitation protocols for the treatment of knee flexion contractures after TKA.

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