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Research Article

Are Computer-Controlled, Pressure Modulated Knee Rehabilitation Machines Valuable Following Knee Arthroplasty?

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Abstract

Background: To determine if a patented new computer controlled, pressure modulated knee rehabilitation machine was more effective, in rehabilitation of total knee arthroplasty, than the continuous passive motion machine utilizing Cochrane Review data.

Methods: Prospective study of 197 patients: 59 outpatient rehabilitation facilities; 155 homebased care, and 7 skilled nursing facilities. Patients were prospectively treated with pressure modulated knee rehabilitation and standard rehabilitation for total knee arthroplasty. Range of motion (RoM) was compared (via ANOVA) with the Cochrane continuous passive motion study. We also evaluated RoM outcomes versus start day of pressure modulated knee rehabilitation use.

Findings: Pressure modulated knee rehabilitation patient's ROM, at 30 days, exceeded 116°; significantly greater than all short-term (6 weeks) Cochrane Review studies (83°). Patients using the pressure modulated knee rehabilitation six or more days after surgery had a significantly lower 14-day RoM than patients who began on days 1-5 following surgery.

Interpretation: The pressure modulated knee rehabilitation patients increase their RoM following total knee arthroplasty significantly more than continuous passive motion users.

Keywords: Knee Arthroplasty Total; Knee Joint; Rehabilitation; Recovery of Motion; Range of Motion.

Introduction

Constant passive motion (CPM) machines have been used for decades. Initially, CPMs were supposed to accelerate rehabilitation, including range of motion (ROM) and function following total knee arthroplasty (TKA). However, numerous studies show the CPM lacks efficacy following TKAs [1-5]. Here, we document a new computerized pressure modulated knee rehabilitation (PMKR) device, an FDA Class 1 medical device, (the X10TM, Halley Orthopedics, Franklin, MI, United States of America) [Figure 1,2] that utilizes pressure to increase RoM and strength of patient's affected knees. The device is set up to range the patient's knee through an arc using a pressure the patient finds comfortable. The patient controls the machine and only the patient can authorize an increase in the arc or pressure. As patients increase their RoM, within each 30 minute session, they routinely increase both arc and the pressure.

Figure 1: Patient using the in-home X10 knee rehabilitation machine.

Figure 2: X10 screen and kill switch.

The CPM is used in bed and can be quite painful. Indeed, O'Driscoll [6] argued that patient should be given sufficient Analgesics, while using the CPM, that pain is not an issue. However, the CPM is not efficacious perhaps due to its inability to maintain alignment between patient and machine. As patients were to use the device for up to 20 hours/day [6] the patient will likely destroy the alignment [7-11] if the machine doesn't. Ironically, CPM patient's knees were not moved through the entire preset arc (68-76%) [12], and this may explain why there is no published optimal protocol for its use.

In contrast, the PMKR device is used in a seated position; with the leg fixed in three places so the alignment between patient and device is maintained and the patient experiences the full RoM. At the ends of the RoM, when the periarticular fluid is under the greatest pressure, the PMKR device slows its progression and dwells, allowing the fluid to escape the knee. Patients use the PMKR machine for three, 30 minute sessions/day. The on-board computer records patient performance with each stroke of the machine and reports this data to an Oracle server allowing surgeons and physical therapists to track daily performance. This would also enable discharge, not by number of visits, but by measures of actual outcomes, which would prevent over and under treatment and could provide enormous cost savings.

Here, we compared data from the PMKR to those in the Cochrane Review [13] on CPM rehabilitation groups and control groups, to see if the use of the PMKR, combined with standard rehabilitation, enhanced the acquisition of functional ROM following a TKA.

Objective

Here, we sought to determine

1. The effectiveness of the PMKR in a sample of total knee arthroplasty patients

2. If the PMKR machine provided greater gains in ROM than CPM machines, when both were used in standard rehabilitation programs. To accomplish this, we compared our results to the Cochrane Review results

3. The optimal timing for the use of the PMKR machine

We focused on improving early RoM because this is the crucial time for getting patients to a RoM that avoids a manipulation under anesthesia (MUA), or other procedures [14]. Surgeons vary in their criteria for performing an MUA, but MUA's may be performed in the first month following TKA [14].

Gaining RoM early should also decrease the strength deficit caused by either insufficient RoM or arthrogenic muscle inhibition (AMI). The average TKA patient has a 30% strength deficit at one year which can persist for 6-13 years [15,16]. Ventline et al. [17] found that the PMKR device also enhances RoM in the six months to the one year range when compared to the same surgeon's CPM patients, or the Cochrane Review [13]. Improved early RoM also hastens patients' ability to perform both isotonic and eccentric exercises, as well as functional exercises in weight-bearing and closed-chains. Function will then improve faster with less long-term disability [18-23]. There are two basic mechanisms at work here, first removing periarticular fluid enhances RoM, and simultaneously reduces AMI enabling voluntary muscle activation; permitting leg exercise which then further reduces the fluid and strengthens the neural stimulation creating a virtuous cycle that quickly removes fluid, restores RoM and strength [24-27].

Methods

Demography

We did a prospective study of 197 consecutive patients (March 2012-March 2016) utilizing the PMKR machine in their rehabilitation following unilateral TKA. We have daily, or near daily measurements on 102 patients. This was a large case series and we used the Cochrane Review as a control. Seven patients were in a skilled nursing center, 155 had home care and 59 were treated at outpatient clinics. Some of the home care patients were subsequently treated in an outpatient setting, hence the numbers do not sum to 197. Forty-five percent of the patients were male and 55% were female. Average age of males was 65.4 years; while the average age of females was 64.5 years.

Patient selection

TKA patients were taken consecutively, from five different surgeons, as machines became available. Patients were excluded if they developed an infection or deep vein thrombosis, had dementia, or if the original diagnosis was not osteoarthritis. We also recorded the patient age at time of surgery and the affected leg. The data were collected via the PMKR's onboard computer and physical therapists' medical charts. We conducted a repeated measures analysis of variance of the PMKR data to determine if we could pool the data from the five surgeons. The variances were homogenous; results were independent of surgeon, and accordingly pooled.

Diagnosis and treatment

All of the included patients received the same physical therapy treatment, which included active and passive exercises including both eccentric and isotonic program as well as closed-chain exercises and the following standard protocols

- Gait training
- Balance and proprioceptive training

- Activities of daily living (ADLs --as donning and doffing clothes, transfers in and out of bed, chairs and car
- Ascending and descending stairs
- Ambulation on uneven surfaces and ramps. If needed, proper use of modalities such as a cold pack with compression, or soft tissue mobilization to help reduce scarring at the surgical site or internal adhesions were included.

All patients utilized for statistical analyses completed at least 12 or more treatments with the PMKR as well as participated with the a fore mentioned physical therapy. Patients were guided and monitored when utilizing the PMKR. The total time on the machine was somewhat variable, but averaged approximately 30-minutes per treatment, plus or minus 5-minutes, three times a day at home, (TID); or, once, 2-3 times per week (B-TIW), at outpatient physical therapy. Patients had formal physical therapy on a B-TIW basis, and were also given home programs that were modified as they progressed.

Study variables

Flexion RoM is measured by the PMKR with each stroke of the machine to within 1° and recorded on the machine's onboard computer along with the date, so we could determine how many days after surgery the patient began using the PMKR, the total times a patient used the machine, and if there were gaps in the usage. We also recorded the RoM the day following surgery that the patient began PMKR therapy. The patients discontinued the home use of the PMKR when starting formal outpatient physical therapy, normally 2-3 times per week post TKA.

Specific aims

We had three specific aims

- To determine if usage of the PMKR leads to an increase in the RoM
- To determine if rehabilitation with PMKR is more efficacious than CPM use
- To determine the optimal time period in which to begin PMKR therapy.

Data analysis

When analyzing the continuous data we used the days on the machine in a repeated-measures ANOVA. When comparing data at a benchmark, e.g., 30 days, we utilized a one-way ANOVA allowing us to utilize more of data. We utilized regressions to compare days on the machine with the RoM.

Data for the CPM was obtained from the Cochrane Review [2,3,20,28-35]. We compared our data to The Cochrane Review studies because they used only randomized studies in their meta-analysis and the relatively large number of patients included in their study (>1400) provided us with a high quality control and consensus series of outcomes to compare our results against. The Cochrane Review divided studies into three groups: short-term studies (six weeks or less), medium-term (six weeks to six months) and long-term (greater than six months). The Cochrane Review listed the mean, standard deviation and number of participants in each study. This allowed us to perform t-tests comparing the 30 -day mean for the PMKR patient against the mean of each of the short-term studies. We tested each pair of variances using Levine's test. If the variances were homogeneous, we used Student's test for equal variances, and unequal sample size and where variances were heterogeneous, we used a t-test for unequal sample sizes and unequal variances. We only had 2 patients utilize the machine for 40 or more days and thus could not compare the PMKR to the Cochrane medium or long term (60, 90 days data).

We used a one-way ANOVA to determine how quickly patients reached 110° RoM depending upon the day after surgery they began treatment. We used 110° of RoM as surrogate for functional ADL. To determine the optimal time period in which to begin PMKR therapy we divided patients into start groups. Those who began using the PMKR on Day 1, Day 2, Day 3, Day 4, Day 5, or Day 6 or longer days after surgery. We used the 14-day RoM as the dependent variable. The data were analyzed using an analysis of variance and a Student-Neuman -Keuls post hoc test.

Results

Efficacy of the PMKR

The average daily RoM of 102 patients along with the 95% confidence intervals are given in [Figure 3]. The patients who begin using the PMKR usually within the first five days averaged 3°- 5° gains of RoM/day for the first five days of PMKR use. Within three weeks the average PMKR patient had a RoM of more than 110° and was no longer a candidate for an MUA. We examined the cumulative frequency of patients who have exceeded 90° or 110°. By 30 days, over 97% of patients have exceeded 90°, and 75% of patients have achieved or exceeded 110°. The majority of the PMKR patients were beyond the MUA RoM window.

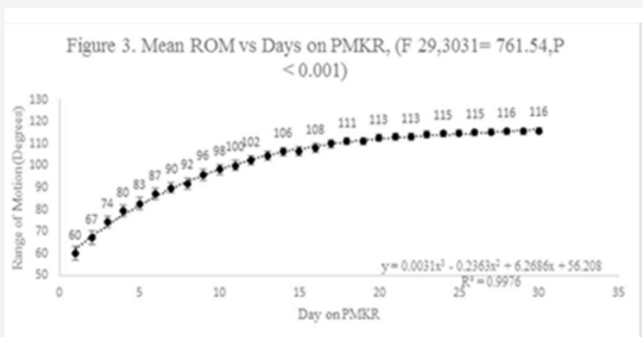

Figure 3: Knee range of motion vs days on PMKR X10.

No other device provides daily data and so there really is nothing to which we can compare this daily data. Accordingly, we have compared the data on specific days to the regularly reported episodic measurements that surgeons or physical therapists make in their office.

CPM vs PMKR

We compared data in the Cochrane Review on CPM rehabilitation groups and their control groups with the PMKR to see if this device, combined with standard rehabilitation, would enhance the RoM following a TKA. PMKR patient RoM at 30 days of usage exceeds 115° and was significantly greater than all the six weeks (short-term) studies cited in the Cochrane Review, [Table 1]. At 30- 60 days the PMKR patients exceeded 117° and was significantly greater than all of the Cochrane medium-term studies.

Table 1: Comparison of ROM Outcomes for X10a PMKR vs. CPM.

Study	Date	Mean	Lower CI	Upper CI	t-test	P
Brun-Olsen	2009	85.0°	80.1°	89.9°	7.38	0.01
Chiarello	1997	74.7°	64.2°	85.2°	6.83	0.01
Denis	2006	83.3°	78.6°	88.0°	8.1	0.01
Huang	2003	81.1°	75.6°	86.6°	8.14	0.01
Lau	2001	78.0°	72.4°	83.6°	8.82	0.01
Lenssen	2008	89.9°	86.2°	93.3°	6.57	0.01
May	1999	79.7°	77.6°	81.9°	10.23	0.01
McInnes	1992	82.0°	78.6°	85.4°	8	0.01
Ng	1999	67.0°	62.4°	71.6°	15.01	0.01
Sahin	2006	82.0°	78.5°	85.5°	9.48	0.01
X10a (30day episode)	2015	116.3°	113.8°	118.9°		

When should PMKR therapy be initiated

We divided patients, with daily data, according to the initial RoM into four groups: less than 30° RoM, 30-49°, 50-69° RoM and 70°+ RoM. RoM was calculated as the angle of greatest flexion (AGF) minus the angle of greatest extension (AGE) based on the RoM achieved the second day the patient used the PMKR, [Figure 4].

There are two important and related points regarding Figure 4.

- Regardless of the starting RoM, all patients made progress
- The data converge.

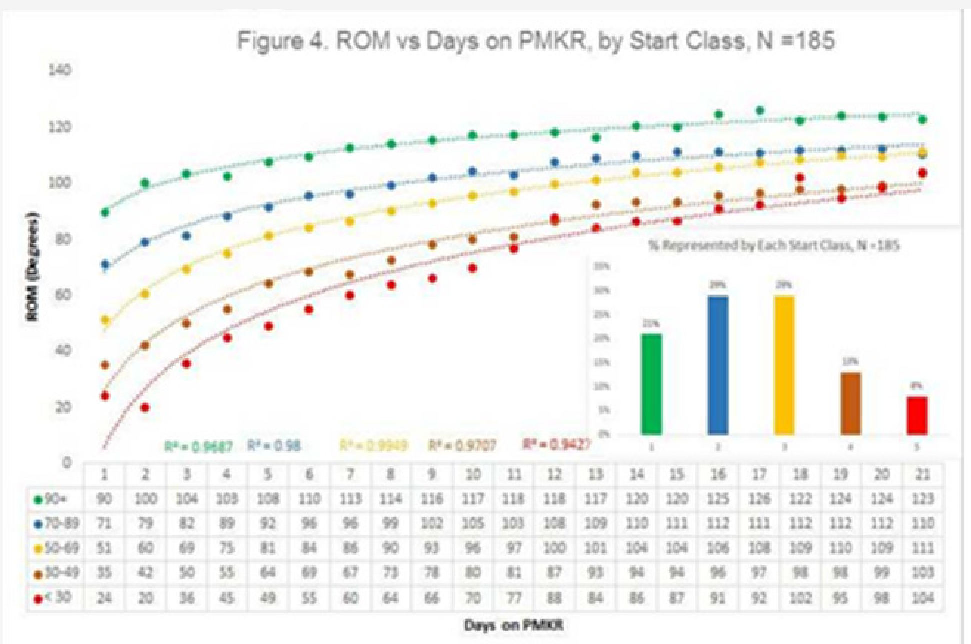

Figure 4: Range of motion vs days on PMKR X10 by start class. Inset shows the proportion of patients in each start class. Start classes were based upon the range of motion as assessed on the second day that the patient used the machine. Start class 1= >90°, class 2= 70°-89°, start class 3 = 50°-69°, start class 4= 30°-49°, start class 5 is < 30°.

Convergence occurs because the lower the initial RoM, the greater the slope over time. Patients, who began with 70°+ RoM, had a slope of 12.5 times the natural logarithm of the days of use. Patients who began with less than 30° RoM had a slope of 33.4; indicating that although some patients begin slowly, the PMKR and its ability to enable patients to gradually expand RoM without triggering additional pain and inflammation. Accelerated restoration of RoM enables physical therapists to then begin work on strength, power, endurance and functional capacity of the knee earlier.

We found that the use of PMKR gave patients more rapid and greater gains in RoM compared to the CPM, this then promotes improved strength, power and endurance and reduce complications, e.g., longer rehabilitation times, and development of intra-articular scar tissue which might lead to MUA [4,5].

Early Gains in RoM & Days to Discharge

We next looked at the discharge RoM of PMKR patients, [Figures 5]. We used 110 degrees of RoM or greater as a surrogate for discharge day from physical therapy. Most of our patients achieved 110 degrees or greater range of motion. Achieving this RoM took, on average, less than one month of rehabilitation, Figure 5.

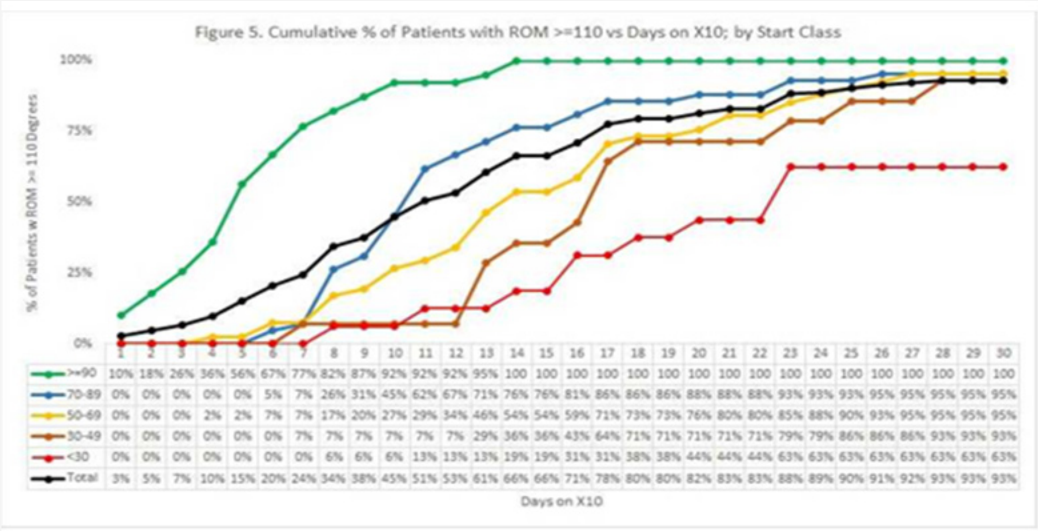

Figure 5: Shows the cumulative frequency of patients who have achieved 110° range of motion by start class. 110° is used as a surrogate for the activities of daily motion.

Early rehabilitation is very important for patients' overall outcomes and satisfaction following TKA. When the RoM improves, especially through early rehabilitation, improvements in long-term function and strength in both flexion and extension can be achieved more easily [22]. General RoM improvements correlate with overall patient-reported outcomes which improve dramatically [18,23,36].

Using normal distribution to determine the percentage of patient with greater than 110° ROM

We used the mean (116°) and a standard deviation for PMKR to generate normal distribution, [Figure 6]. Similarly, we used the means, standard deviations and sample sizes to pool all 10 of the short-term Cochrane studies and to generate a normal distribution about the mean (81°), Figure 6. Most of the PMKR curve lies above 110 indicating that within a month of use, most patients will be able to resume many of the ordinary activities of daily living and physical therapists should be able to begin strengthening, balance and other exercises earlier in the recovery than if a CPM were used.

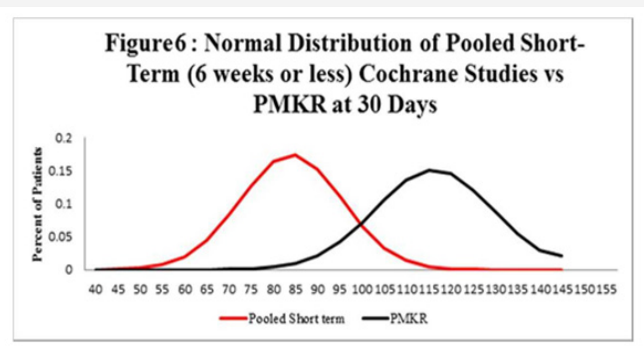

Figure 6: We pooled the short-term studies from the 2014 Cochrane report and compared the normal distribution about the mean using the pooled standard deviation to the normal distribution about the mean ROM for the PMKR X10, using its standard deviation.

Initial RoM and Gains in RoM

We also examined the day following surgery that the patients began using the PMKR machine and the patients 14-day RoM. Patients were divided into start day groups: Day 1, Day 2, Day 3, Day 4, Day 5, and Day 6 or Later. There was a significant difference among the start dates, ($F_{5,120}$ = 6.47, P<0.001), with Student-Neuman-Keuls post hoc testing showing that patients who began on day 6 or later, after surgery, had significantly lower 14-day RoM than the other five start day groups which did not differ from each other, [Figure 7].

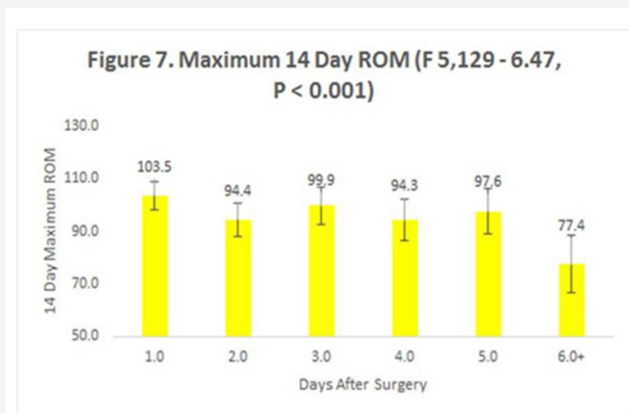

Figure 7: Shows the ROM at 14 days based upon the day after surgery that the patients began using the machine.s

The PMKR addresses not only the RoM issue; it also helps address the strength, power and endurance problems that are commonly present following TKA [20, 37-40]. PMKR eccentric and isotonic exercises can help address chronic muscle impairments. The ability to add eccentrically-based rehabilitation exercises included in the PMKR can improve overall function dramatically following TKA surgery [19, 38]. These are likely to help particularly with strength and endurance which is needed during functional activities [20,39].

Compliance: Just over 100 patients used the PMKR machine in their home. Because the data is sent to a server every time a patient uses the machine, we can monitor compliance. The use-at-home patients used the machine 92% of the days the machine was in the home.

Discussion

Efficacy of the PMKR

The PMKR is a recently patented new tool that can be used along with standard rehabilitation care and shows excellent compliance and improvement in RoM for patients undergoing TKAs secondary to severe OA, particularly patients who begin using the PMKR in the first 5 days following surgery. Early gains in RoM are important, because they can preclude the need for MUA's and other techniques for regaining RoM. Over 97% of PMKR patients exceeded 90° RoM at 30 days.

We compared data in the Cochrane Study on constant passive motion (CPM) rehabilitation groups and their control groups with data from the PMKR to see if the use of this device, combined with standard rehabilitation, would enhance the RoM following a TKA. PMKR patients RoM at 30 days of usage exceeded 115° and was significantly greater than all of the six week (short-term) studies cited in the Cochrane Report [13], which averaged 83° at six weeks Table 1. Patients who had the lowest initial RoM gain RoM faster than patients who had greater initial RoMs and the data converged for all initial RoM classes. Thus, the PMKR machine strongly reduces the among-patient variation in RoM, providing a more uniform outcome.

CPM lacks efficacy

Orthopedic surgeons and rehabilitation specialists/physical therapists have been searching for decades to find a device that would improve RoM following TKAs. Much of this has been involved research regarding CPMs and their inclusion in the rehabilitation process. During this time, numerous studies have shown that CPM machines do not aid in rehabilitation and improve RoM following TKAs [2,3,5,20,29,35,41-44]. Typically, there was no statistically relevant advantage in using a CPM unit along with a standardized rehabilitation program for patients with unilateral TKAs. It has been recommended by most of these researchers that CPMs not be used.

Intensive Rehabilitation

Some researchers have recommended intensive functional rehabilitation, which improves not only RoM, but also improves functional ability after uncomplicated primary TKA [21,45].

This intensive rehabilitation is one of the reasons that we followed through with evaluation of the PMKR and its inclusion in a standard, or even an aggressive, rehabilitation program. Patients receive 90 minutes of intensive therapy a day, far more than in most other settings.

Future studies should focus on standard rehabilitation with and without the use of PMKR. The optimal time to initiate the use of PMKR with the elimination of CPM use.

Study Limitations

The primary limitation of the study is that we used a literature control. The primary comparisons were that of multiple studies showing that standard rehabilitation care with or without CPM is essentially the same [1-3, 42,46-51].

Conclusions

The PMKR has shown to be an effective modality in the rapid improvement in functional RoM of unilateral, uncomplicated TKAs. With rapid and gentle increases in RoM, the PMKR enables patients to progress quickly in their rehabilitation process towards improvement in overall functional goals. The use of PMKR and a standard TKA protocol rehabilitation program was far superior to the use of the CPM and the standard rehabilitation program, particularly when patients begin use within five days following surgery. Future studies should focus on standard rehabilitation with and without use of PMKR with elimination of CPM use.

Acknowledgement

We thank Paul Ewing, BS, MBA and David Halley, MD for their assistance in developing the protocols for the use of the PMKR machine.

Ethical Approval

This study was approved by the Western Institutional Review Board®

Clinical Trial Registration Number

1152136 The device is FDA approved for the indicated usage in the United States.

Conflict of Interest

No Conflicts of interest.

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