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Intraarticular Quasi-Constant Force Tension in Total Knee Arthroplasty Regardless of Joint Gap and Knee Size

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Abstract

Balancing soft tissues in the knee with the patella in place and with regularly applied force helps surgeons make decisions for positioning knee components in a manner that is friendly to soft tissues. A novel intraarticular device has been developed for achieving a balanced knee joint over the range of motion of the knee without requiring manual adjustments during surgery. Quasi-Constant force output was generated by the device at usual joint gaps for the knee sizes encountered during total knee arthroplasty.

1 Introduction

In total knee arthroplasty (TKA), instability and stiffness are key drivers of patient dissatisfaction and revision (Golladay, et al., 2019) (Anon., 2021) (Le, et al., 2014). To improve patient outcomes, navigated ligament balancing techniques in TKA reference patient soft tissues and bony landmarks to position implants intended for preserving natural kinematics of the knee using stereotaxic instrumentation. To achieve this target, surgeons have used lamina spreaders, spoons or spacer blocks to apply tension between the tibia and the femur during the procedure to plan bone cuts. Other options for applying force between the femur and tibia include modifiable tensioners, but these devices require adjustment to accommodate a changing joint gap and require the adding of shims or the turning of a knob while requiring complex extraarticular apparatuses or eversion of the patella. An intraarticular device that can maintain a consistent joint tensioning force without eversion of the patella or any adjustment can reduce cognitive burden on the surgeon while continuing to reference the patient soft tissues for making clinical decisions. Within the proposed device, nearly constant force can be achieved by balancing two different internal mechanisms: a Hookian spring that increases force output as it is compressed and a non-Hookian spring mechanism that is defeated as it is compressed. The objective of this study was to report in-vitro verification testing of the novel

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device that generates nearly constant condylar forces independently on both medial and lateral compartments at typical tibiofemoral gap thicknesses encountered during TKA.

2 Methods

Using an Instron load frame and a 10kN calibrated load cell, a tibiofemoral gap was simulated by mounting size 0, size 3 and size 6 Exactech® femoral trials in extension with 30PCF bone foam at 9mm, 12mm, and 15mm distances from a flat stainless-steel platen representing a tibial resection (Figure 1). The size 0 and size 6 femoral trials represent the minimum and maximum femoral sizes for the subject implant system while size 3 is the most used femoral size, and the 9mm, 12mm and 15mm gaps represent typical tibial insert implant thicknesses selected during a primary TKA. Five advanced ligament balancing intraarticular devices were placed within the gap to generate an in-vitro force. The force was recorded three times for each gap value and for each femur size for a total of 135 measurements. Finally, the force values were compared to the analytical solution that was used for device design.

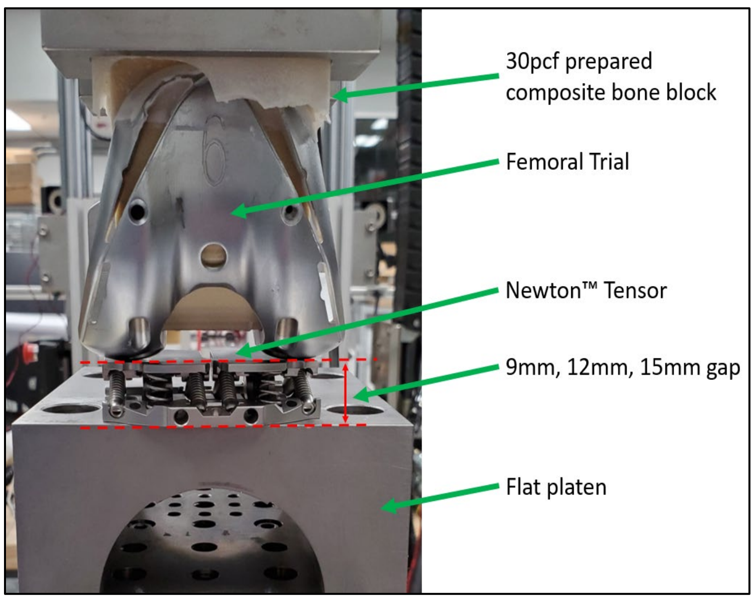

Figure 1. Test Setup

3 Results

Regardless of knee size and gap, the average force measurement combining both force plates for the Newton device across all measurements was 34.8lbf with a 1.64lbf standard deviation. At 9mm, 12mm and 15mm gaps, the average force values were 33.5lbf, 36.8lbf and 34.0lbf respectively with standard deviations of 0.57lbf, 0.87lbf, and 0.88lbf respectively. Deviation from the average force was 1-7% depending on the gap size and implant size. Though changes in force output were limited across all gap sizes and femoral implant sizes, the change in femoral implant size had a lower impact on force than change in gap size (Figure 2).

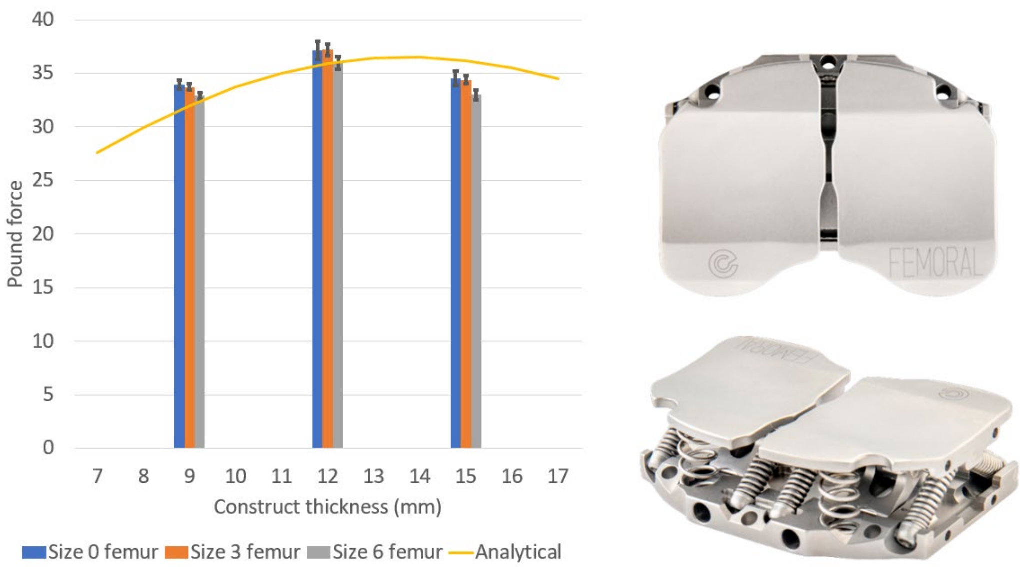

Figure 2 Left | Test results, Right | Device Manifestation

4 Discussion

Balancing the knee joint with a constant force on both medial and lateral compartments allows for obtaining patient specific information about the knee joint; which can be leveraged for setting up the femoral cut parameters. While conventional devices have allowed for obtaining the soft tissue information at specific flexion angles, this intraarticular spacer may facilitate the acquisition of patient data without everting the patella or adjustment while automatically applying a consistent force throughout an entire range of motion. This study is limited because the force data was acquired with rectangular gaps while the knee was only positioned in extension. Future work should be focused on acquiring force data at multiple flexion angles and across a gradient of variable gaps in cadaver medium. While the output was not perfectly constant across all knee sizes and gaps, the force magnitude was similar to the force output of currently marketed devices (Gong, et al., 2019) (Roth, et al., 2015) (Shalhoub, et al., 2019) (Shalhoub, et al., 2018). Use of a quasi-constant force tensor in surgery could allow for improvement of patient outcomes by providing real time patient data about the knee balance and kinematics during TKA.

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