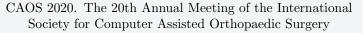


EPiC Series in Health Sciences

Volume 4, 2020, Pages 240–245





Frequency of Soft-Tissue Releases and their Effect on Patient Reported Outcomes on Robotic-Assisted TKA

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Abstract

Soft tissue releases are often required to correct deformity and achieve balance in total knee arthroplasty (TKA). However, releasing soft tissues can be subjective, highly variable and is perceived as an 'art' in TKA. The objective of this study was to compare the rate of soft tissue release required to achieve a balanced knee in tibial-first gapbalancing versus conventional, measured resection TKA, and its effect on outcomes.

Soft tissue releases were documented and reviewed in 1256 robotic-assisted gapbalancing and 85 robotic-assisted measured-resection TKAs. Knees were stratified by coronal deformity (varus: >2° varus; valgus: >2° valgus). Rates of releases were compared between the two groups and literature. A subset of these patients were also enrolled in a prospective study. KOOS outcomes were captured pre-operatively and at 6M post TKA.

The frequency of soft tissue release was significantly lower in the robotic gapbalancing group, with 21% of knees requiring release versus 40% (p=0.001) in the robotic measured resection group and 67% (p<0.001) for conventional measured resection. Pre-operative KOOS scores were similar between groups, however 6M scores showed a significant improvement in QOL, Sports and Symptoms scores in knees not released.

Robotic assisted TKA with predictive gap balancing was found to reduce the number of releases across all coronal angles compared to conventional instruments. Furthermore, performing a soft tissue release rather than bone resection to achieve

balance, correlated with worse outcomes. Further research is required to understand when imbalance should be corrected with bone resection adjustment versus soft tissue release.

1 Introduction

Soft tissue releases are often required to correct deformity and achieve gap balance in total knee arthroplasty (TKA) [1]. However, the process of releasing soft tissues can be subjective and highly variable and is often perceived as an 'art' in TKA surgery [2]. Releasing soft tissues also increases the risk of iatrogenic injury and may be detrimental to the mechanically sensitive afferent nerve fibers which participate in the regulation of knee joint stability.

Measured resection TKA approaches typically rely on making bone cuts based off of generic alignment strategies and then releasing soft tissue afterwards to balance gaps [3]. Conversely, gap-balancing techniques allow for pre-emptive adjustment of bone resections to achieve knee balance thereby potentially reducing the amount of ligament releases required. No study to our knowledge has compared the rates of soft tissue release in these two techniques.

The objective of this study was to compare the rates of soft tissue releases required to achieve a balanced knee in tibial-first gap-balancing versus femur-first measured-resection techniques in robotic assisted TKA, and to compare with release rates reported in the literature for conventional, measured resection TKA [4]. A secondary objective was to compare patient reported outcome scores (KOOS) at six months (6M) follow-up for patients that had one or more soft tissue release performed versus those that did not.

2 Methods

The number and type of soft tissue releases were documented and reviewed in 1256 robotic-assisted gap-balancing and 85 robotic-assisted measured-resection TKAs as part of a retrospective multicenter study. In the robotic-assisted gap balancing group, a robotic tensioner was inserted into the knee after the tibial resection and the soft tissue envelope was characterized throughout flexion under computer-controlled tension (Figure 1a). Femoral bone resections were then planned using predictive ligament balance gap profiles throughout the range of motion (Figure 2b), and executed with a miniature robotic cutting-guide. Soft tissue releases were stratified as a function of the coronal deformity relative to the mechanical axis (varus knees: >2° varus; valgus knees: >2°). Rates of releases were compared between the two groups and to the literature data using the Fischer's exact test

A subset of these patients were also enrolled in a prospective study. KOOS outcomes were captured pre-operatively and at 6M post TKA. KOOS subscores were compared between the released and non-released groups using the Wilcoxon rank-sum test.

3 Results

The overall rate of soft tissue release was significantly lower in the robotic gap-balancing group, with 21% of knees requiring one or more releases versus 40% (p=0.001) in the robotic measured resection group and 67% (p<0.001) for conventional measured resection [2] (Figure 3). When comparing as a function of coronal deformity, the difference in release rates for robotic gap-balancing was significant when compared to the conventional TKA literature data (p<0.0001) for all deformity

categories, but only for varus deformities for robotic measured resection with the numbers available (varus: 22% vs 40%, p=0.001; neutral 10% vs 27%, p=0.08, valgus 28% vs 50%, p=0.09). The rate of releases in all robotics cases exceeded 50% in patients with a pre-operative varus > 10° and valgus > 7.5°. Within these limits the release rate was 19.7%.

Pre-operative KOOS scores were similar between knees that were released and not released (Quality of Life (QOL): 26.7 vs 30.2, p = 0.19, Sports: 21.4 vs 26.6 p = 0.06, Symptoms: 53.8 vs 52.6, p = 0.59, Pain: 51.4 vs 51.9, p = 0.80, Function: 53.7 vs 57.9, p = 0.06). Post-operative 6M outcome scores however, showed a significant improvement in QOL, Sports and Symptoms scores in knees that were not released (QOL: Δ = 10.2, p = 0.001; Sports: Δ = 11.3 p = 0.009, Symptoms: Δ = 4.4, p = 0.02) (Figure 4).

4 Discussion

Robotic assisted TKA with predictive gap balancing was found to reduce the number of releases required to achieve a balanced knee across all coronal angles compared to conventional instruments. Furthermore, performing a soft tissue release rather than bone resection to achieve balance, correlated with worse KOOS outcomes. These findings are supported by a recent study which found implant realignment to balance joint pressures as opposed to ligamentous release correlated with improved 1-year KSS functional scores [5].

Higher release rates in knees with greater pre-operative deformity may explain some of the difference in post-operative outcomes [6]. However, the similarity in pre-operative outcomes indicates the overall score and change in score was greater in those not released. Further data capture and analysis of patients with high pre-operative deformity is required to compare the outcomes of knees with and without soft tissue release.

A limitation to this study is the magnitude of the release is not reported. The number and extent of release may impact the soft tissue injury and may further affect outcomes [7]. Further research is required to better understand what degree of imbalance should be corrected with bone resection adjustment

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Figure 1 (top) Digital balancing device (BalanceBot) used to tension to knee after tibial resection; (bottom) Femoral resections planning screen showing predicted post-operative ligament balance in green box

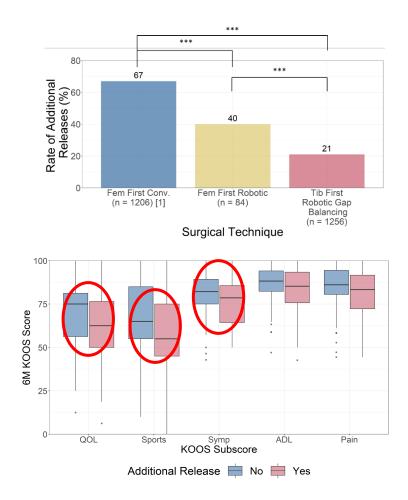


Figure 2 (top) Comparison of soft tissue release rate for all pre-operative deformities. All techniques are significantly different from each other, with tibia first gap balancing with predicted joint gaps reporting the lowest release rate. (bottom) Comparison of 6 Month outcomes for knees in which a soft tissue release was performed and not. Significant differences are circled in red.

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