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Reliability of Laxity Acquisitions Under Controlled Load Environment During Navigated Total Knee Arthroplasty

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Abstract

Proper soft tissue balancing during total knee arthroplasty (TKA) is critical to ensure successful clinical outcomes. As an attempt to offer an intra-operative characterization of the soft-tissue envelope, a novel method enables the possibility of acquiring the joint laxities under a quasi-constant distraction force throughout the entire range of motion. TKAs were performed using a computer-assisted orthopaedic surgery (CAOS) system on a fresh-frozen human cadaveric specimen. A total of 60 laxity acquisitions were performed by 5 surgeons using the CAOS system. There was an excellent interobserver reliability of the laxity acquisitions (ICC=0.913-0.992). Similarly, the intraobserver reliability was also excellent (ICC=0.846-0.984). These findings demonstrated that the acquisition of the knee joint laxities under the proposed controlled load environment is highly reliable.

1 Introduction

Proper soft tissue balancing during total knee arthroplasty (TKA) is critical to ensure successful clinical outcomes (Gustke, et al., 2014) (Golladay, et al., 2019) (Anon., 2021) (Le, et al., 2014). However, most intra-operative techniques still rely on the subjective assessment of the joint balance and only encompass a few discrete angles of flexion (e.g., full extension and 90˚ of flexion). As an attempt to offer an intra-operative characterization of the soft-tissue envelope, a novel method enables the possibility of acquiring the joint laxities under a quasi-constant distraction force throughout the entire range of motion and then to leverage these acquisitions as inputs for the set-up of a patient-specific surgical plan. The aim of this study was to determine the inter- and intraobserver reliabilities of acquiring the knee joint laxities under controlled load environment during navigated TKA.

2 Methods

TKAs were performed using a computer-assisted orthopaedic surgery (CAOS) system on a fresh-frozen human cadaveric specimen (age 66 years, female). At the trial reduction stage, a trial femoral component was impacted onto the prepared distal femur and a novel intra-articular tibial distractor was introduced into the joint space. The distractor features 2 independent mechanically actuated compartments intended to apply (once released) a quasi-constant distraction force (nominally set-up at 20 lbs per compartment) regardless of the joint gap. Then, the limb was manually taken through a full arc of motion and the corresponding joint laxities were acquired by the CAOS system (see Figure 1). The manipulations were successively performed by a total of 5 surgeons (3 seniors and 2 juniors) on 3 occasions on 2 knees across both medial and lateral condyles. The inter- and intraobserver reliabilities were assessed using intraclass correlation coefficients (ICCs) and 95% confidence intervals (CIs) (Koo & Li, 2016).

Figure 1. Proposed method of acquisition of the laxity envelope under controlled load environment throughout the arc of motion

3 Results

A total of 60 laxity acquisitions were performed using the proposed method. Regardless of the compartment (i.e., medial or lateral), there was an excellent interobserver reliability of the laxity acquisitions (ICC=0.913-0.992) (See Table 1A). Similarly, the intraobserver reliability was also excellent (ICC=0.846-0.984) (See Table 1B). It was observed that the reliability of the laxity acquisitions of the medial compartment was higher than the reliability of the laxity acquisitions of the lateral compartment but didn’t reach statistical significance (p=0.385). Finally, the experience level of the observer had no impact on the reliability of the acquisitions (p=0.626).

A)	Knee		Compartment	ICC	95%CI
	#1		Medial	0.992	0.979-0.996
			Lateral	0.969	0.919-0.985
	#2		Medial	0.966	0.886-0.985
			Lateral	0.913	0.801-0.954
B)	**Experience**	**User**	**Compartment**	**ICC**	**95%CI**
	Senior	#1	Medial	0.984	0.964-0.991
			Lateral	0.926	0.858-0.958
		#2	Medial	0.965	0.905-0.983
			Lateral	0.935	0.882-0.962
		#3	Medial	0.943	0.847-0.973
			Lateral	0.846	0.614-0.926
	Junior	#4	Medial	0.976	0.953-0.986
			Lateral	0.956	0.939-0.969
		#5	Medial	0.911	0.850-0.945
			Lateral	0.938	0.913-0.956

Table 1: A) Details on interobserver reliability of the laxity acquisitions, B) Details on intraobserver reliability of the laxity acquisitions

4 Discussion

These findings demonstrated that the acquisition of the knee joint laxities under the proposed controlled load environment is highly reliable. This excellent reliability is assumed to be multi-factorial. First, the applied distraction force provides a stability of the joint during the acquisition due to consistent tension across the joint. Next, the intra-articular design of the distractor allows the possibility of maintaining the extensor mechanism in place, which also contributes to the stability of the joint. Finally, unlike other methods of laxity acquisition that sequentially apply stressed varus and valgus, the present method is intended to be performed under neutral manipulation, which greatly facilitates the acquisitions. In addition to its high reliability, this method distinguishes from other advanced methods (Roth, et al., 2015) (Shalhoub, et al., 2018) by offering a streamlined hardware with a fully intra-articular actuation mechanism.

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