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Feeling Better After TKA: Reference chart for remotely collected pain scores

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Abstract

Remote patient monitoring, using wearable devices and connected patient engagement platforms has the potential to improve timely clinical decisions. Data collected from multiple patients, including using the remote engagement platforms themselves, can be used to produce evidence-based reference to support clinical decisions. While some normative references for functional measure currently exist for total knee arthroplasty (TKA), these are still lacking for VAS pain scores. Therefore, VAS pain scores on a 10-point Likert scale were analyzed for 66 patients, each reporting at least five scores in the 180 days following surgery. These were used to produce a normative recovery model for total knee arthroplasty patients. A nonlinear mixed effects model was fitted, whereby the response variable is assumed to be distributed following a beta-binomial distribution. The population mean trend showed a with wide dispersion in the first few days following surgery, showing scores ranging throughout the 10-point scale. After the first week, the expected pain score steadily decreases, resulting in a score no higher than one in 50% of the population beyond 90 days after surgery. The fitted model allows referencing individual patient's pain scores at different stages of recovery, against the model's predicted distribution. This approach can support early detection of patients that significantly deviate from the reference model and be a useful integration into clinical decision support software tools.

1 Introduction

Increase in demand for Total knee arthroplasty (TKA) over the last decades (El Bitar et al., 2015; Pabinger et al., 2015), and of the associated costs and pressures on medical resources and staff, has

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led efforts to optimize postoperative protocols, including reduction of hospital stays, while preserving quality of care. Remote patient monitoring, through a variety of wearable devices and connected patient engagement platforms, provide clinicians with additional visibility to patients' recovery. These allow collection of patient recovery data at higher granularity and lesser staff costs, than can be achieved traditionally. Because of the high granularity of the data collected, complications and deviations from the expected recovery path can potentially be detected earlier than with practice visits alone, allowing to manage patients by exception rather than following a standardized trajectory for all patients. Also, remote patient monitoring can be particularly valuable in conditions such as during the recent COVID-19 pandemic, by enabling continued patient monitoring while limiting disease transmitting contacts.

Assessment of TKA patient's recovery and early detection of complications includes comparing functional (e.g., range of motion) and/or patient reported (e.g., pain scores) metrics against historic / population-based expectation at given stages of recovery. Clinicians often have implicit expectations about patient recovery trends on which they base their clinical decisions. For example, the assignment of physiotherapy exercises, or assessment of progressing recovery, is often based on patients' range of motion capabilities at certain recovery milestones. These are usually based on clinicians' own experience resulting from exposure to their practice's patient population. However, it can be advantageous to have more formal normative recovery expectation models. Having a common recovery reference across multiple health care professionals, spanning different stages of a patient's postoperative journey, such as clinical assessment, physiotherapy assignment and patient triage, can be advantageous. These models can be particularly useful when integrated in clinical support software tools, that can for example, issue automated alerts that bring attention to patients that deviate from the expectation.

Historical data collected across multiple practices and spatial domains can be leveraged to produce multi-variate normative recovery models and an evidence-based reference to inform clinical decisions at the level of the individual patient. Recognizing their benefits in clinical practice, previous studies have produced normative recovery curves for range of motion in TKA patients. For example, Kennedy at al. (2008) reported curves for the Lower Extremity Functional Scale and the Six-Minute Walk Test up to 1 year following TKA, and Kittelson et al (2020) produced a range of motion reference chart specifically aimed at monitoring postoperative recovery. In addition to functional metrics, patient reported measures (PROMs) have come to the fore to assess clinical outcomes from a patient's perspective, which is believed to better reflect patients' health status and quality of life. Some studies have focused on producing long term prediction (or expectation) for PROMs. For example, Sanchez-Santos et al. (2018) produced a model aimed at prediction Oxford Knee Score (OKS) 12-month after TKA, but their model does not provide a reference trend curve against which to compare patient's observations throughout recovery. While the usefulness of pain score models have been recognized and published for other conditions (e.g., Plan et al 2012. for painful distal diabetic neuropathy), useful references to track patient reported pain scores in the months following TKA are still lacking. In this paper, we present a pain score normative recovery model for data collected using a digital data platform in combination with a patient engagement mobile application (MotionSense™, Stryker), aimed at supporting clinical decisions.

2 Methods

A commercially available database system was used to remotely collect patient reported outcomes from total knee arthroplasty patients, more specifically visual analogue scale pain scores (VAS pain), where 0 represents no pain to 10 representing severe pain. Only data from patients with at least five scores collected in the first six weeks post-surgery were included. Trends were investigated by fitting a nonlinear mixed effects model where the response variable is assumed to be distributed by a beta-binomial distribution:

$$f(x|\alpha,\beta) = \binom{n}{x}\frac{\mathrm{B}(x+\alpha, n-x+\beta)}{\mathrm{B}(\alpha,\beta)}$$

with support $x \in \{0, 1, \ldots, n\}$. This discrete value distribution allows to constrain model's response variable to the non-negative integer domain values of the pain scores by fixing its count parameter n = 10. The beta-binomial distribution can be reparametrized by specifying α and β as a function of the expected value μ and variance ϕ:

$$\alpha = \mu \cdot \upsilon \text{ and } \beta = (1-\mu) \cdot \nu \text{ with } \nu = \frac{\mu \cdot (1-\mu)}{\phi}$$

Using this parameterization, the expectation μ and variance ϕ were modelled as a function of time since surgery including a random effect for patient:

$$logit(\mu) = Z_{\mu}(x) + \delta_p$$

where $\delta_p \sim Normal(0, \sigma)$ is the offset between the individual patient and population level expectation, and

$$\phi = \frac{\mu}{\left(1+e^{-\left(Z_{\phi}(x)\right)}\right)(1-\mu)}$$

The functions $Z_\mu(x)$ and $Z_\phi(x)$ correspond to a six hidden-layer neural networks taking the time of pain score collection (x days since surgery) as input. These functions allow to model non-linear relationships in both the expected value (μ) and dispersion (ϕ) of the pain scores. The model was fitted using a state-of-the-art Bayesian approach allowing for estimation of the fitted parameters' uncertainty, including the neural network weights. Model fitting was carried out using Stochastic Variational Inference (maximizing the evidence lower bound, ELBO) with custom scripts in Python programming language and the PyTorch (Paszke et al., 2019) and Pyro (Bingham et al., 2019) packages. Model performance was assessed by comparing distribution of posterior predictive distribution against the data.

3 Results

Application of the patient selection criteria resulted in 66 patients (39 male, 27 female), with BMI between 20.0 and 35.0 (mean 28.3) and with 14 patients between 50 and 60, 31 patients between 60 and 70, and 21 patients older than 70 years old at day of surgery. The number of pain scores reported was 2,901 with each patient reporting between 5 and 110 (mean 17.3).

As a general trend, pain scores dropped following surgery. The population mean has shown a wide dispersion of scores ranging throughout 10-point scale in the few days following surgery. After the first week, the expected pain score steadily decreased with time, at 90 days after surgery, 50% of patients will not report pain scores higher than one while pain scores higher than five are also very unlikely (less than 5% of the population) after 60 days. The estimated standard deviation of the posterior distribution for random effect δ_p among all patients was $\sigma = 0.76$.

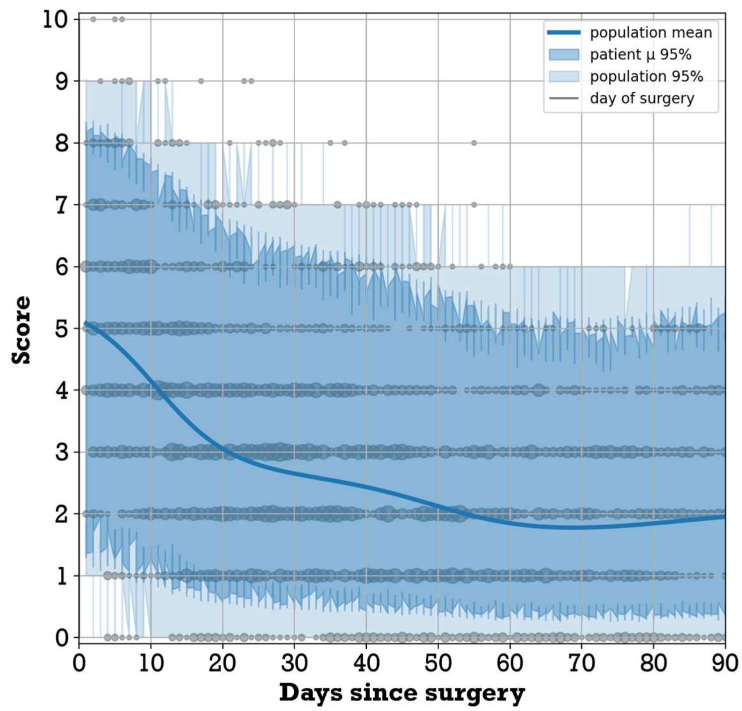

Figure 1: Postoperative pain score trend and expected ranges for the population of patients. Size of grey dots indicate relative number of scores reported. Darker line shows the fitted population mean trend. The shading indicates the 95% intervals for the patient specific mean, obtained from posterior samples.

4 Discussion

While many studies reported in literature focus on longer term patient reported outcomes collected long after the 90-day post-operative window, this study provides insight in short term patient reported VAS pain scores collected using a mobile patient engagement application used for remote patient monitoring. These results give a good indication of the average patient's recovery trajectory following total knee arthroplasty. The fitted model allows referencing individual patient's pain scores against the model's predicted distribution (e.g. Figure 2), either by plotting patient observations on the predicted model's distribution, and/or by calculating a percentile value at a given datapoint reported by a patient. The latter is an objective metric that can be easily understood by health care professionals and can thus be used to support clinical decisions. Moreover, when used in the context of remote patient monitoring, and by setting appropriate thresholds, it can allow early detection of patients that significantly deviate from the reference model and that may require additional or more frequent engagement, effectively allowing to manage patients by exception rather than standard protocols.

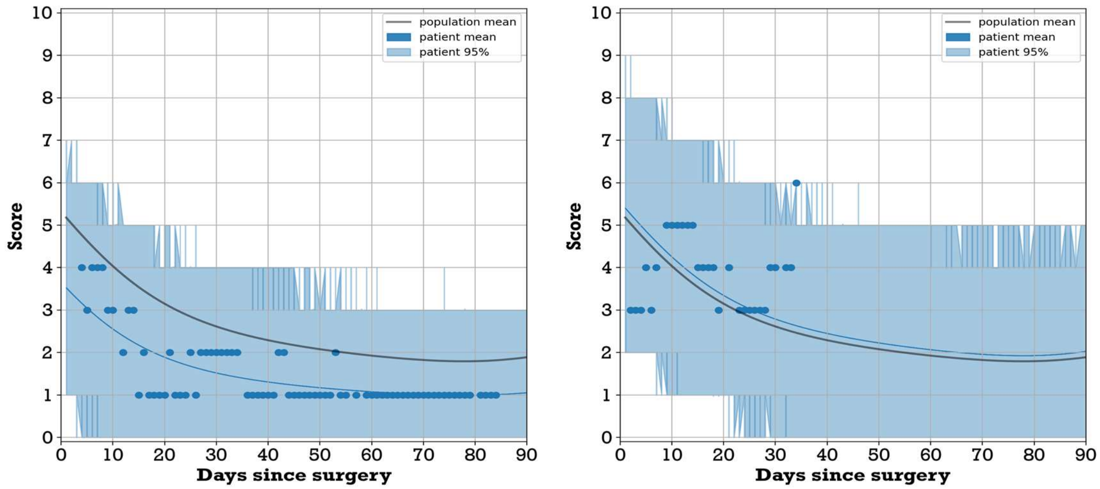

Figure 2: Example of patient adjusted specific pain score trend for two patients. Blue lines show the patient mean trend adjusted from the population mean trend (dark grey lines). Shading indicates the 95% range for patient scores (i.e. 95% of scores are expected to fall within this range). Dots indicate patient reported scores. Left-hand side patient shows a case where all reported scores fall within the model's expected 95% range. The right-hand side patient shows a value at the extreme of the predicted distribution (p(score ≥ 6 @day 34) = 0.004) within a few days of an infection detected by clinical staff.

In the current study, the patient's random effect was estimated as a single offset value with constant variance δ_p throughout the recovery period. This may be further developed to allow more flexibility and better adjusted trend. Other covariates, such as sex, age and BMI may be determinant in shaping the population normative recovery and patient random effects. These effects are not currently explicitly included in the model but may be somewhat captured in the patient random effect parameter. Preoperative conditions and comorbidities have also been shown to determine the outcome of TKA (e.g., Lungu et al., 2016, Jiang et al., 2017, Huber et al., 2019) and deserve consideration as a factor shaping normative recovery curves. Expansion of the presented model including explicit inclusion of the aforementioned factors is currently underway.

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