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Determining the Reliability of a Robotic Surgical System for Producing Good Clinical Outcomes

THINK Surgical, Inc.

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Introduction: A robotic surgical system generally includes: a pre-operative planning software program to generate a surgical plan having a desired position for an implant relative to a bone; and a surgical robot to prepare the patient's bone to receive the implant as planned. One such robotic surgical system is the TSOLUTION ONE® Surgical System manufactured by THINK Surgical, Inc., which assists surgeons in total hip and total knee arthroplasty. The TSOLUTION ONE can accurately mill the bone to receive an implant as planned with minimal error, with overall good clinical outcomes. One particular area of interest is determining the reliability of a robotic surgical system for producing good clinical outcomes (e.g., achieving implant alignment goals, decreased rates of adverse events, decreased rates of revision, etc.) as a function of patient specific factors (e.g., age, gender, BMI, pathology). It may be further beneficial to determine the reliability with additional metrics such as medical staff factors, robotic system factors, or intra-operative data collected during a procedure. The following describes potential methods for determining said reliability.

Methods: A potential method for determining the reliability of a robotic system for providing a good clinical outcome may utilize machine learning (ML) or artificial intelligence (AI). Many ML and AI algorithms are well known in the computational science field. [1] It is contemplated that the reliability of a surgical system for providing a good clinical outcome can be analyzed, measured, or forecasted utilizing one or more ML or AI algorithms with the following inputs:

- Post-operative clinical outcomes from previous or ongoing surgical cases:
  - final implant alignment (e.g., mechanical or kinematic alignment of knee implants); cases of implant subsidence; cases of revision surgery; joint mobility and stability; implant fit, fill, and/or alignment; implant-to-cement contact; bone-to-implant contact; bone ingrowth or osseointegration; error between surgical plan and final implant position; pain indices; and overall improvement in joint functionality.
- Patient specific factors:
  - age; gender; BMI; pathology; bone condition; underlying or pre-existing conditions; behavior; level of physical activity; and medical history.
- Medical staff factors:
  - Staff experience or training; robotic experience and manual experience; and surgical preferences such as implant type and surgical approach (e.g., kinematic alignment vs. mechanical alignment).
- Robotic system or intra-operative factors:
  - robot diagnostics data (e.g., calibration or registration data); preventative maintenance routines; equipment issues; surgical time; number of uses; manufacturing quality/tolerances of robotic tools; operating conditions during a procedure (e.g., motor forces, cutting forces, motor currents, cut paths, feed rates, spindle speeds), and sources of error.

It should be appreciated that not all of these inputs are required, where a select number of these inputs can produce the desired results as specified by an end-user. In light of the above description, one skilled in machine learning or artificial intelligence has the ability to design and develop a software program to classify, analyze, or rank the reliability of a robotic system to provide good clinical outcomes utilizing ML or AI with a plurality of the inputs above. The output of the ML or AI for a particular robotic system may include a summary, average, and/or ranking of post-operative clinical outcomes (past, present, or future) as a function of patient specific factors, medical staff factors, robotic system factors, and/or intra-operative factors. The resulting data may be particularly helpful to manufacturers of robotic surgical systems as well as the surgeons and medical facilities that perform robotic surgical procedures.

References
[1] Dey, Ayon. "Machine learning algorithms: a review." *International Journal of Computer Science and Information Technologies* 7.3 (2016): 1174-1179.