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Low rate of iatrogenic complications during unicompartmental knee arthroplasty with two semiautonomous robotic systems

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ABSTRACT

Background: Intraoperative complications due to utilization of robotic assistance during unicompartmental knee arthroplasty have not been reported. While inadvertent soft tissue injury has been reported during total knee and hip arthroplasty with autonomous style robotic systems, the incidence of these problems with semiautonomous (i.e. surgeon-driven) systems is unknown.
Methods: We report on a series of 1064 consecutive unicompartmental knee arthroplasties performed by one surgeon with either one of two commercially available semiautonomous robotic systems.
Results: There were no soft tissue, bone injuries or other complications related to the use of the robotic bone preparation method. Six complications related to the use of standard computer navigation pins occurred (0.6%) — one pseudoaneurysm of a branch of the tibialis anterior artery, one tibial metaphyseal stress fracture, and four areas of pin site irritation/superficial infection that resolved with a short course of oral antibiotics.
Conclusion: Current semiautonomous robotic methods are safe, with few complications using meticulous surgical techniques.

1. Introduction

The role of unicompartmental knee arthroplasty (UKA) for the management of isolated medial or lateral degenerative arthritis of the knee continues to expand. Riddle and associates have noted an increase of 32.5% in the utilization of UKA during the period between 1998 and 2005 compared to 9.4% in total knee arthroplasty (TKA) over the same time period [1], and that proportion may continue to grow as patient demographics, expectations, quality outcome initiatives, and physician education further shape the field of partial knee arthroplasty. While published series of UKA from high volume centers have shown excellent outcomes and durability [2–4], there is a higher revision rate of UKA compared to TKA and decreased 10-year survivorship among lower volume surgeons according to registry data and large insurance databases [5–7]. While patient selection, surgical indications, quality of cementation and implant fixation, and implant design impact outcomes, these failures commonly result from component malposition and limb malalignment [8–12]. Given the risk of failure of malaligned or imbalanced components in UKA, robotic technologies have emerged to refine bone preparation, optimize component position and quantify soft tissue balance

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[12–28]. Further growth of robotic technologies is predicated on proven clinical value (effectiveness), impact on function and durability, cost efficiency and avoidance of complications with their use (safety).

In the United States, there has been considerable growth in the utilization of semiautonomous robotic technologies for UKA, which are now utilized in roughly 20% of UKAs performed in the United States, and that number is expected to increase to nearly 37% in 10 years (Orthopedic Network News. 2013 Hip and Knee Implant Review. http://www.OrthopedicNetworkNews.com Jul 2013; Medical Device and Diagnostic Industry, March 5, 2015 [http://www.mddionline.com]) [29]. Further, the filing and issuance of patent applications related to robotic technologies and UKA have grown greater than other sectors in knee arthroplasty, representing surrogate indices of interest and development in the field [30]. Broadly speaking, two general types of robotic systems are available for knee and hip arthroplasty, namely autonomous and semiautonomous systems [13,16,18]. Autonomous systems are capable of performing the surgical procedures without surgeon intervention other than the initial input of parameters [13,16,18,31–35]. Semiautonomous systems are ultimately guided and acted upon by the surgeon while the system establishes some sort of constraint within predefined boundaries with either haptic resistance or burr tip exposure and velocity control [16,18,21,22]. Currently, only semiautonomous robotic systems are approved by the United States Food and Drug Administration (FDA) for use in UKA, TKA and patellofemoral arthroplasty (PFA).

Despite the reported success in achieving desired implant alignment and positioning with current robotic systems, concern has been raised regarding the safety of robotic preparation. This stems from publications regarding autonomous robotic systems, which have been shown in TKA and total hip arthroplasty (THA) to have a relatively high incidence of iatrogenic soft tissue complications [31–34]. While some extent of soft tissue injury has been reported in UKA and TKA with conventional methods [7,36], the considerably higher rate of particular soft tissue injuries in these aforementioned studies has been among the barriers to broader adoption of robotic technology for knee and hip arthroplasty.

To date, no studies have reported the incidence of inadvertent soft tissue injuries caused by semiautonomous robotic technologies. Our hypothesis is that the incidence of iatrogenic injury caused during semiautonomous robotic surgery in UKA is low, since the systems are under direct control of the surgeon, with safeguards preprogrammed to avoid inadvertent bone preparation. The purpose of this study is to determine the incidence of soft tissue or bone injury directly caused by using robotic bone preparation tools in UKA with either of two contemporary commercially available semiautonomous robotic systems.

2. Materials and methods

A retrospective review of a prospectively maintained database – that included intraoperative details and perioperative adverse events – of consecutive cases of UKA performed utilizing one of two semiautonomous robotic knee systems from March 2008 through March 2017 was undertaken. All surgeries were performed by a single experienced high volume knee arthroplasty surgeon, at several hospitals and surgery centers, and the study included all cases, including those done during the period of initial technology adoption. Institutional review board approval was received prior to chart review. Intraoperative records, outpatient medical records and the patient database were reviewed to determine the incidence soft tissue injuries that occurred during the robotic procedures.

The systems included the Mako robotic arm (Stryker, Ft. Lauderdale, FL) and the Navio handheld robotic sculptor (Smith and Nephew, Memphis TN). Mako is an image-based system that requires a preoperative computed tomography (CT) scan to aid in preoperative mapping and planning; Navio is image-free inasmuch as a preoperative CT scan is unnecessary, with all planning and mapping performed intraoperatively. Both systems are considered semiautonomous. Using anatomic features of the condylar surfaces of the knee and alignment indices of the limb, the parameters for volume and orientation of bone to be removed are input into the system by the surgeon. The robotic tools are used like a sculpting tool to remove pre-determined diseased bone and cartilage. It is controlled by the surgeon who manipulates the robotic apparatus and turns the burring tool on and off in real time, while the system protects against inadvertent bone removal by either haptically constraining the robotic arm (Mako) or modulating the exposure and/or speed of the burr within a protective sheath (Navio). In our series, all medial UKA cases were performed through a minimally invasive, quadriceps-sparing approach; lateral UKAs were performed through a midline skin incision and a lateral parapatellar arthrotomy.

3. Results

During the time period from March 2008 to July 2013, the senior surgeon performed 492 consecutive UKAs performed with Mako semiautonomous robotic system and from July 2013 to March 2017, 572 consecutive cases were performed using Navio semiautonomous robotic system, for a total of 1064 robotically assisted UKAs during that time period. Ninety-two percent were medial UKA; eight percent were lateral UKA. All but two patients either had formal postoperative follow-up at six weeks or were reached by phone or email. Two patients could not be reached for six-week follow-up. Ninety-one percent of patients had three-month follow-up.

There were no inadvertent or iatrogenic soft tissue injuries, bone injuries or other complications related to the use of the robotic bone preparation tools. There were no cases in which the robotic tool was abandoned during the case due to a complication or perception that structures were at risk during the use of the robotic systems. Six complications related to the use of standard computer navigation pins occurred (0.6% of cases) — one pseudoaneurysm of a branch of the tibialis anterior artery, which presented as lower extremity swelling eight weeks after surgery and resolved with endovascular treatment; one tibial metaphyseal fracture, which healed with bracing and protective weight-bearing; and four pin sites that displayed several weeks of irritation

and delayed healing, potentially representing superficial infections that resolved with a short course of oral antibiotics. There were three cases of early peri-incisional cellulitis that resolved with a short course of oral antibiotics. There were two late hematogenous deep infections that occurred six months and 12 months after surgery that required staged revision to TKA. Three patients required manipulation under anesthesia within three months after surgery.

4. Discussion

While robotic-assisted surgery has improved the accuracy of bone preparation in UKA and TKA compared to conventional techniques, robotic system efficiency and safety are paramount concerns that should be considered when contemplating the additional expense of these technologies [22,37]. Several studies observed a relatively high incidence of soft tissue or osseous complications in total joint arthroplasty [31–34], resulting in the need for secondary surgeries in many cases and deleteriously impacting the clinical outcomes. In two studies of the autonomous robotic system for TKA, inadvertent disruptions of the patellar tendon occurred in three percent and eight percent, respectively [31,33]. This is considerably greater than the incidence of patellar tendon disruption following TKA with conventional methods that have ranged from 0.17% to 1.4% [38,39] and after UKA, which has been reported to occur in less than 0.02% of cases [7]. Furthermore, in a series of THAs performed with an autonomous robot, 13% required revision for recurrent dislocation related to gluteus medius tendon rupture [32], highlighting the need to study safety of available robotic systems in joint arthroplasty. Other series of total joint arthroplasty with autonomous robotic technology did not find an increased incidence of soft tissue complications associated with bone preparation [36,40–43]. The reported soft tissue problems may be related to inadequate soft tissue dissection, exposure and protection of adjacent structures.

Soft tissue complications are uncommon with semiautonomous robotic methods of preparation because anatomic bone and joint surface mapping are performed either entirely intraoperatively under direct visualization (Navio) or with a supplemental CT scan (Mako) and the robotic tools have safeguards to limit inadvertent bone preparation beyond the areas of surgical mapping, even using minimally invasive surgical techniques. Since the end-effector tools are under direct control of the surgeon, the preparation tools in these semiautonomous systems are not turned on until they are in proximity to the programmed area. Additionally, their protective mechanisms – haptic control or modulation of the burr exposure and speed – protect against inadvertent injury to soft tissues beyond the planned area. With regard to the knee, even with these intrinsic safeguards, it remains important to appropriately position soft tissue retractors to minimize collateral damage, such as deep to the medial collateral ligament during adjacent bone preparation. Judicious use of retractors, as observed in the current study, coupled with the intrinsic safety mechanisms of the systems, should eliminate or minimize iatrogenic soft tissue injury, even utilizing limited incision surgical approaches. Reasonable use of soft tissue retractors was the norm, using standard retractors during the procedure. In the senior surgeon's experience, typically fewer retractors can be used when performing robotically assisted surgery with semiautonomous technologies compared to conventional methods due to the inherent safeguards of the combination of accurate surface mapping and surgeon control of the robotic tool. The absence of robotically related complications is substantially lower than those reported in databases analyzing tens of thousands of conventionally performed UKA [7].

Several studies have found that accuracy with semiautonomous robots can be achieved early in one's clinical experience in UKA. Karia et al. found that when inexperienced surgeons performed UKA on synthetic bone models using robotics, the mean compound rotational and translational errors were lower than when conventional techniques were used. In that study, among those using conventional techniques, although surgical times improved during the learning period, positional inaccuracies persisted. On the other hand, robotic assistance enabled surgeons to achieve precision and accuracy when positioning UKA components, irrespective of their learning experience [19]. Others have found that surgeons experienced with conventional methods of UKA can achieve greater precision when first using robotic methods in a clinical setting [13–30]. Further, conservative bone preparation, an important goal of UKA, is more achievable with robotic than conventional methods [28]. This may eventually prove to enhance durability, since placing the tibial insert on stronger bone has been shown to be biomechanically advantageous. Additionally, using smaller tibial inserts makes ultimate revision to TKA easier and minimizes the need for augments and stems. Few have reported clinical outcomes with robotics in UKA [14,26], but none have specifically addressed intraoperative complications. This current study is the first to show the safety of semiautonomous robotic technology in a large cohort of over 1000 patients. One recent cadaveric study found that haptic constraint of a standard saw blade, combined with preoperative and intraoperative surface mapping, provided adequate protection against damage to the medial and lateral collateral ligaments, posterior cruciate ligament, and patellar tendon in six cadaveric knees that underwent TKA with a semiautonomous robotic technique by a surgeon with no prior experience with the system [44].

Unlike studies that reported higher complication and revision rates due to malalignment or malpositioning early during a surgeon's first cases after adopting minimally invasive UKA with conventional instrumentation [45,46], we found immediate precision upon adopting these two surgical robotic technologies [20,23], and no soft tissue complications at any stage of the senior surgeon's clinical experience caused directly from the use of either robotic method of surface preparation with limited, but appropriate, soft tissue retraction. While our low incidence of navigation pin-related complications had no direct relation to the use of the robotic tools per se, since they were inserted manually, our observed pin-related complications need to be considered as potential occurrences when using robotic-assisted navigation.

This study had several shortcomings. This was a retrospective study, and while it reviewed a prospectively maintained database that included intraoperative details and perioperative adverse events, no standardized complication collection form was created prior to surgery, and the complications reported could be underestimated since they depended on operative and clinical

notes or patient reports during postoperative visits or phone interviews. Additionally, most of these reported complications are immediate postop and at short-term follow-up within the three-month follow-up, which occurred in 91% of patients.

In conclusion, the emerging role of robotic assistance for UKA continues to expand, but safety of the available technologies in addition to cost effectiveness and system efficiency must be weighed in the balance against the additional accuracy and precision provided by the robotic systems. Based on this and several other studies, it appears that semiautonomous robotic systems offer a desirable safety profile and low rate of intraoperative complications. Further study of semiautonomous systems in TKA and THA in vivo is needed to determine their safety profiles for these expanded indications.

Ethical statement

This study was reviewed and approved by an Institutional Review Board.

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