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PURPOSE: There are no FDA approved plastic surgery indications for the Da Vinci Robotic Surgical System (Intuitive Surgical, Sunnyvale CA). This prospective study, designed in consultation with the FDA, is intended to demonstrate safety and efficacy in latissimus muscle harvest for 510(K) approval.

METHODS: Patient demographics, robotic specific operative details and times, as well as overall complications were recorded. Baseline upper extremity function and disability including range of motion, Medical Research Grade grade strength, and quickDASH scores were compared at baseline and specific follow-up intervals. A visual analog scale was used to examine post-operative pain. Analysis included a difference in differences technique between operative and non-operative extremity function with paired t-test.

RESULTS: Fifteen patients enrolled, as recommended by the FDA, with a history of radiation in 93.3% (n=14/15). Mean follow up to date is 12.7 months. Assist access was performed via prior mastectomy/axillary incision (mean = 9.1 cm) with 0/15(0%) requiring conversion to open approach. 87% (n=13/15) of patients underwent concomitant symmetry procedures with mean operative and console times of 309.3 and 67.4 minutes respectively. No significant difference was detected between baseline and 3–6 month follow-op QuickDASH (p= 0.47) and Quick-DASH Work modules (p=0.58). Visual analog scores for pain demonstrated progressive improvement to near baseline at 3–6 month follow-up. No statistically significant differences were detected in function including range of motion and MRC strength grade. Complications included infection (n=2/15, 13.3%), hematoma (n=1/15, 6.7%), wound dehiscence (n=1/15, 6.7%), and seroma (n=1/15, 6.7%).

CONCLUSION: Latissimus harvest using the Da Vinci Robot is safe and effective with low complication rates and no significant residual functional limitations. Robotic LD harvest should be considered among the indicated uses for this device. Baseline vs. 3–6 month follow-up

J. Shuck: None. M.W. Clemens: None. J.C. Selber: None.

QS27

Utilizing Statistical Process Control to Study the Progression of Institutional Situational Awareness Through Anonymous Incident Reporting

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PURPOSE: The impetus for widespread focus on patient safety reached its apex in the early 1990s when the Institute of Medicine sent shockwaves with their report, To Err is Human. They estimated nearly 100,000 deaths occurred from preventable medical errors every year. Bagian and colleagues took the lessons learned from industries such as aviation and introduced them to healthcare. As a result, anonymous incident reporting (AIR) was implemented in Healthcare to foster a culture of safety. Pioneers like Sutcliffe and Singh took this a step further by studying factors like situational awareness (SA) and its role in creating High Reliability Organizations (HRO). The purpose of this project is to determine if the application of statistical process control (SPC) can be applied to anonymous incident reporting to study institutional situational awareness.

METHODS: Our institution’s AIR protocol begins with any employee filing an anonymous online safety report. This report is assessed and directed to the appropriate manager by patient safety officers. An action aimed at systemic safety improvement is undertaken, and the feedback is shared at workgroup meetings. The Veterans Administration National Center for Patient Safety (NCPS) maintains a database of all AIR reports. All AIR reports from our institution from December 2012 to October 2016 were collected and trended. Critical events were tracked utilizing VASQIP’s Critical Incident Tracking Notification System (CITNs). VASQIP defines CITNs as: death in operating room (OR), death from hemorrhage within 24hours, incorrect surgery, retained surgical item, OR fire, and OR burn. Data was evaluated by month and by quarter for percent change and compared to observed critical events (CITNs). Events were trended as a statistical process control (SPC) chart and a logarithmic regression was performed for progression of AIRs per month.

RESULTS: There was an exponential increase in total AIRs (1st mo-1, 6th mo-6, 12th mo-706, 18th mo-914, 24th mo-1156). The reporting rate peaked at 9 months (1425%
increase from prior quarter). In contrast, the highest number of CITNs were observed early and significantly decreased over time (1st year-5, 2nd year-2, 3rd year-1, 4th year-1). The course of our AIR program began slowly, but as feedback to reporters increased, reporting and situational awareness increased exponentially. This result demonstrates the fruits of a successful AIR program in establishing situational awareness.

CONCLUSIONS: SPC analysis can be applied to anonymous incident reporting to study the progression of institutional situational awareness. Application of our model can give other institutions a method to evaluate not only their AIR program but also their situational awareness.

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QS28

Additive Drilling Significantly Improves Mechanically-Tested Bony Stabilization in Translational Spine Models

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STATEMENT OF PURPOSE: Surgical fixation of implants into bone to treat skeletal pathology has positively influenced the well-being of patients and continues to be the basis of orthopaedic rehabilitation. Surgical fixation is dependent on osseointegration, the anchorage of bone around implant. Osseointegration evolves with primary and secondary stability between implant and bone: the initial mechanical interlocking between bone and implant and subsequent bone growth through the healing chambers of the implant, respectively. Osseointegration is dependent on multiple factors such as implant macrogeometry, host bone quality, and drilling techniques1. Implant geometries and bone quality have been well described, but different drilling techniques are not well explored. The traditional subtractive drilling techniques render the bony spicules excavated impractical, while additive techniques utilize them as nucleating surfaces for new bone. Therefore, we chose to investigate the effect of additive drilling on implant insertion.

METHODS: Utilizing a translational animal model, 64 implants were installed in the lumbar spine of 8 adult sheep (n=8/animal) bilaterally, with each pedicle screw measuring 4.5mm in diameter x 45mm length. The animals were separated into two time points, 6 and 12 weeks in-vivo. The left side of each lumbar vertebra underwent traditional subtractive drilling, while the right underwent additive drilling. The animals were sacrificed with anesthetic overdose, and the vertebrae were removed en bloc. Pullout strength was measured through mechanical testing using a universal testing machine. For histological analysis, non-decalcified histology was utilized. Biomechanical testing results were recorded and analyzed as mean values with the corresponding 95% confidence interval values (mean ± CI). Pull-out strength were compared using several factors of time in vivo (6- and 12-weeks) as well as surgical drilling method -subtractive and additive.

RESULTS: Mechanical pullout strength collapsed across all time points delineated no significant difference in outcomes between vertebrae. However, when comparing mechanical stability between additive and subtractive drilling at 6-weeks, there was significantly greater pullout strength for the additive group versus the subtractive group. The additive Group measured ~ 390 N, meanwhile the subtractive group only measured ~300 N. Furthermore, at the 12-week time point similar results were seen as the additive group had pullout strength of ~320 N and the subtractive group had ~230 N. All results were significant with \( p < 0.05 \). Demonstrates the initial histological evidence of increased bone growth in the additive group versus subtractive group.

CONCLUSION: Mechanical pullout testing demonstrated that additive drilling provides better implant anchoring and stability compared with the subtractive group. The trend that pullout strength was greater at 6 weeks than that at 12-weeks can be explained by the further development of secondary stability at the 12-week time point. Transverse histological sections of (left) subtractive and (right) additive drilling protocols. 1.Coelho PG, Jimbo R. Osseointegration of metallic devices: current trends based on implant