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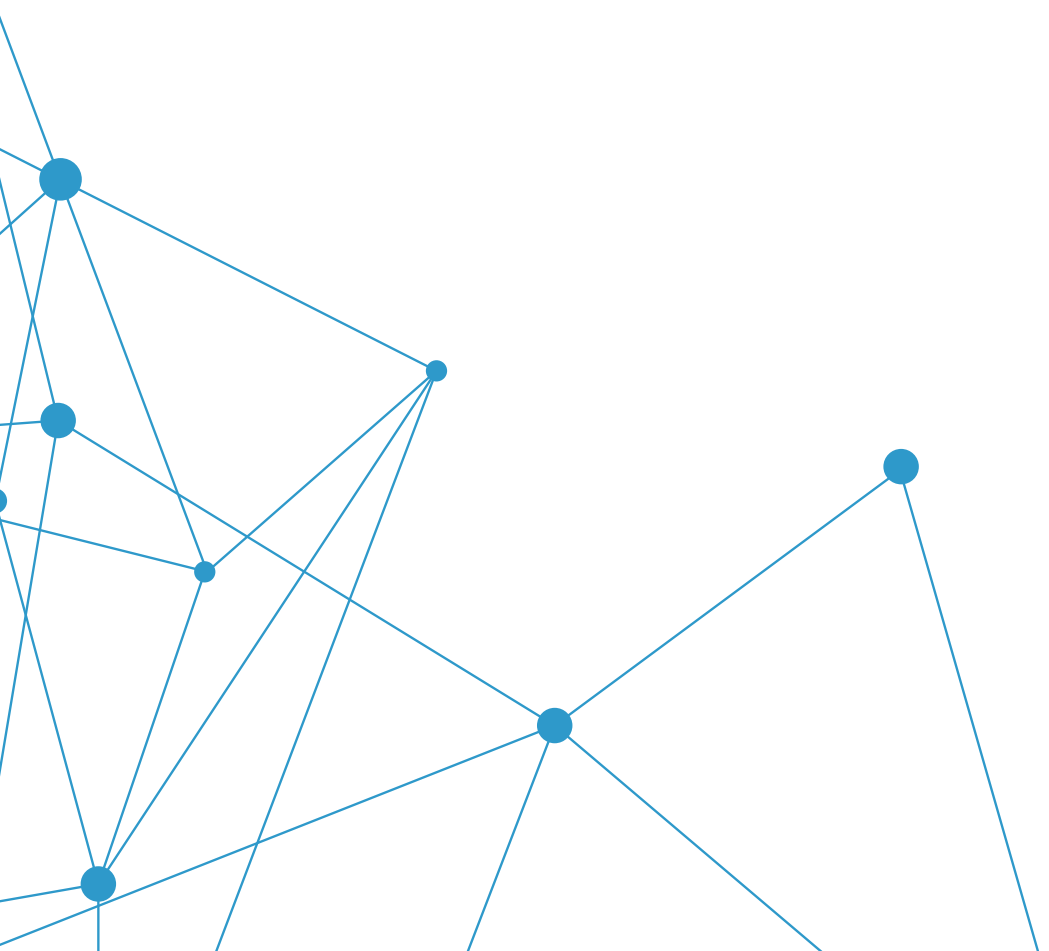
VALUE ANALYSIS BRIEF
WalterLorenz® Surgical Assist Arm



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FINALLY, THE FREEDOM, FOCUS, AND CONTROL TO OPERATE.

The WalterLorenz Surgical Assist Arm is a bionic, electromechanical device that enables steady tissue retraction and surgical site optimization.

- Designed to provide confidence and support for an optimized workflow
- Alleviates the retraction burden on the OR team
- Streamline OR workflow through controlled, consistent, and steady retractor placement
- **WalterLorenz Surgical Assist Arm is a bionic, electromechanical device for use in the OR designed to streamline OR workflow, optimize OR efficiency, and provide surgeons with control of the position of surgical instrumentation.**
- The WalterLorenz Arm may be used for tissue retraction in a wide range of surgical applications including shoulder arthroplasty, total and partial knee replacement, direct anterior and posterior hip arthroplasty, robotic-assisted total knee arthroplasty, maxillofacial, thoracic, spine, foot & ankle and trauma.
- This device is designed to offer a streamlined OR workflow that promotes efficiency and provides OR staff and surgeons with the support they need during the surgical case by providing consistent, controlled, and steady retraction without obstructing the surgical field of view.

Executive Summary

OR team size, composition, and productivity are all factors that impact overall OR efficiency and costs.[1]

- OR team size has a direct impact on the procedure time – with all other factors held constant, increasing the number of OR staff increases the procedure time.[1] Each additional OR team member may prolong the procedure time by up to 15 minutes[1], which would result in an increase in costs by up to $615/procedure*.
- Procedure time is also impacted by the composition of the OR team
  - A consistent team reduces procedure time and may also impact post-operative outcomes, such as hospital stay and readmissions, compared to inconsistent OR teams.[2]
- OR turnover time is an important factor in OR efficiency:
  - Intraoperative turnover of OR nursing significantly increases procedure time and may increase OR costs by up to $3,411/procedure*.[3]
  - Using a specialized team, such as orthopedic-specific staff, is significantly more efficient than a non-specialized team to turnover the OR suite in between cases. A dedicated OR staff may save up to 11 minutes in turnover time, potentially saving up to $450/turnover*.[4]
- Improving OR productivity by reducing procedure delays is a key driver of overall OR efficiency and often results in reducing staff overtime.[5,6] Overtime pay is costly and may result in hospitals exceeding their annual budgets.[7]

Hospital employees, including OR staff and surgeons, experience work-related pain and injury.

- Hospital workplace injuries are common and result in missed workdays[8] – OR staff and surgeons commonly report musculoskeletal pain and injuries due to physical demands of their jobs.[9-11]
- The physical demands of the OR may result in increased rates of leaves of absence, turnover, and early retirement for nurses and physicians.[11-13]
- Maintaining awkward postures during surgical procedures, including holding surgical instrumentation, greatly contributes to pain and injuries reported by OR nurses and surgeons which may lead to increased rates of absenteeism and turnover.[14-17]
  - Ergonomic risks of holding surgical instrumentation, such as retractors, have been reported for both surgeons and OR staff.[18,19]
- Controlled, consistent, and steady retraction may be difficult to maintain during a surgical procedure as OR staff and surgeons adopt inappropriate working postures that increase fatigue, and may result in musculoskeletal pain and may result in inconsistent retraction during the surgical procedure.[18-20]
- Inconsistent retraction causes fluctuations in applied forces placed on soft tissue surrounding the surgical site, which may result in a risk of tissue damage or nerve injury.[21-23]

OR staff injuries directly and indirectly impact hospital costs.

- Workers' compensation resulting from hospital work-related injuries may cost the US healthcare system $2 billion per year.[24]
- Employee turnover places substantial burden on hospitals, given vacancies left by OR nurses and surgeons take considerable time to fill.[25,26]
- Additionally, indirect costs—including costs associated with employee turnover, such as recruitment, hiring, and training of new employees, and loss of productivity and morale—are substantial.[24,41]

*OR cost per minutes = $37.45 (2014 USD) adjusted to $41 (2020 USD) using US Bureau of Labor Statistics inflation calculator: (https://data.bls.gov/cgi-bin/cpicalc.pl)

Challenges Facing Hospitals: Efficiency in the OR is a Key Concern

Key Takeaways:

- OR team size, composition, and productivity are all factors that impact overall OR efficiency and costs[1-5]
- Increasing the size of the OR team directly correlates with increases in procedure time and also increases in costs[1,27]
- Consistency in OR team members impacts procedure time and post-operative outcomes[2]
- OR turnover time impacts OR efficiency: intra-operative turnover of OR staff increases procedure time, and patient turnover between cases is more efficient with specialized staff[4]
- Reducing procedure delays will improve productivity and may have downstream effects on staff overtime costs[7,28,29]

Lean, Consistent, Efficient OR Teams Are Essential to Optimize Overall OR Efficiency

OR efficiency is affected by several modifiable factors relating to the OR team:

- **OR team size:** several multiple regression analyses have demonstrated that, when all other factors are held constant, each additional team member in the OR significantly lengthens procedure time.
  - In a retrospective analysis of 399 laparoscopic procedures (2005-2007), each additional team member predicted a 15.4-minute increase in procedure time.[1]
  - In a retrospective analysis of 587 general surgery procedures (2007-2008), each additional team member added was estimated to prolong the procedure time by 7.3 minutes.[27]
  - Every minute in the OR costs up to $41*, so increases in procedure time quickly raise overall OR costs.[5] Based on the above examples, hospital costs due to prolonged procedure time may result in an increase of up to $615/procedure*.
- **OR Team Composition:** dedicated, predictable surgical teams are associated with better performance.
  - In a retrospective review of 1,923 knee and hip arthroplasties (2008-2010), team consistency (defined by the nurse and surgical technologist working with a given surgeon during the study period) was an independent predictor of procedure time, as well as postoperative outcomes: inconsistent teams had a higher probability of prolonged procedure time (odds ratio 1.52), prolonged hospital stay (odds ratio 1.51), and more readmissions (adjusted odds ratio 1.42).[2]

*OR cost per minutes = $37.45 (2014 USD) adjusted to $41 (2020 USD) using US Bureau of Labor Statistics inflation calculator: (https://data.bls.gov/cgi-bin/cpicalc.pl)

- **OR team turnover:** increased turnover of surgical team and patient turnover between cases are associated with significant increases in procedure time.[3,4]
  - In a retrospective review of 235 lobectomies (2008-2012), nursing turnover (defined as the replacement of one nurse by another during the case) was independently associated with:
    - Significantly increased surgical time (mean increase in time from skin incision to closure; 53.7 minutes, P=0.03) as well as the total procedure time (mean increase in time between patient entrance and exit from OR; 83.2 minutes, P=0.002)[3]
    - Based on the data from this study, increase in time due to nursing turnover may increases OR costs by up to $3,411/procedure*.
  - A retrospective review of 621 sequential hand surgeries with 227 turnover times (2011-2012) demonstrated that turnover time (defined as turnover time between cases) was significantly reduced with orthopedic-specific staff vs non-orthopedic staff, with an average time-savings of 11 minutes (P=0.005).[4] The reduction in turnover time reported in this study, may result in potential savings of up to $450/turnover*.

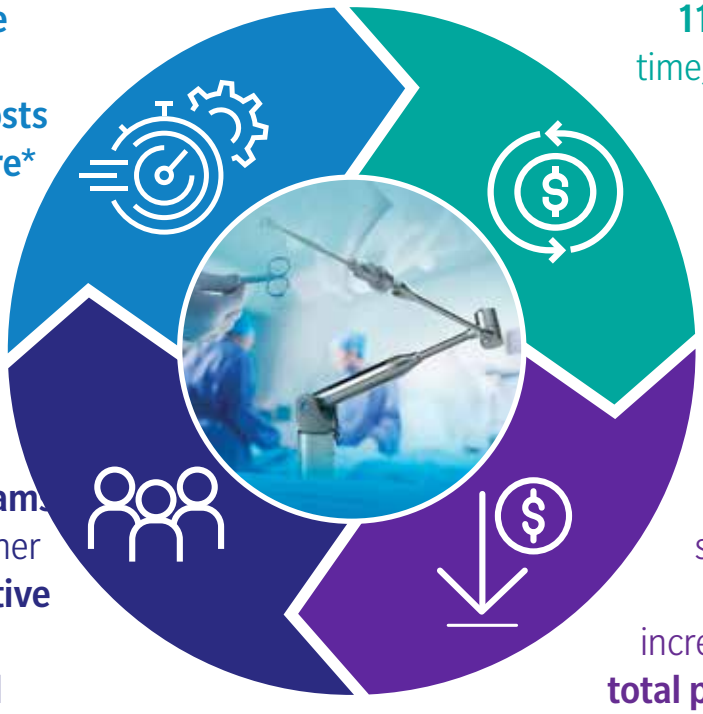
- **OR Productivity:** ORs operate with slim margins, leaving little room for delays or any other inefficiencies.
  Even slight delays accumulate quickly, leading to overtime, adding to costs and creating a negative ripple effect in the OR.[5,6]
  - A study evaluating 1,531 elective cranial or spinal surgeries performed between 2000 and 2009 found that initial delays in the day's first scheduled surgery were associated with significantly more delays in the day's subsequent surgeries (P<0.001).[28]
    - These delays lead to significant overtime; a study examining OR processes at a larger tertiary hospital in upstate New York found that total overtime pay for OR nursing staff resulting from delays was nearly 200% over-budget, and totaled nearly $1.4 million.[7]
  - In addition to impacting OR costs, excessive overtime contributes to employee burnout and turnover, and reduced staff availability in high-need situations; combined, these negative effects on hospital staff can negatively impact patient safety and satisfaction.[30,31]
    - In a US study of approximately 400 full-time registered nurses, 81% of shifts during a two-week reporting period involved some overtime. Working overtime increased the risk of making at least one error (P=0.0005); and working more than 40 or 50 hours per week increased the risk further (P≤0.0001). Most commonly reported errors included provision of medication (58%) and procedural errors (18%).[29]

*OR cost per minutes = $37.45 (2014 USD) adjusted to $41 (2020 USD) using US Bureau of Labor Statistics inflation calculator: (https://data.bls.gov/cgi-bin/cpicalc.pl)

How much is a lean, efficient, consistent OR team worth?

Each **additional team member** in the OR may **prolong procedure time** by up to **15 minutes**[1], potentially **increasing costs by up to $615/procedure***

Presence of a **dedicated OR staff** may save up to **11 minutes**[4] in turnover time, potentially **saving up to $450/turnover***



Procedures performed with **inconsistent OR teams** are associated with a higher risk of **prolonged operative time (52%), prolonged hospital stay (51%), and more readmissions (42%)**[4]

Nursing turnover is associated with significantly **increased surgical time** (mean increase 53.7 minutes) and **total procedure time** (mean increase 83.2 minutes)[3], potentially **increasing costs** by up to **$3,411/procedure***

*Based on estimate average cost of OR time: $41/minute (adjusted to 2020 USD)

Hospitals operate with slim margins, often less than 5%, "which leaves little room for wasted time and resources". As annual healthcare costs increase by double digits, "it is more important than ever for hospitals to operate at peak efficiency".[32]

*OR cost per minutes = $37.45 (2014 USD) adjusted to $41 (2020 USD) using US Bureau of Labor Statistics inflation calculator: (https://data.bls.gov/cgi-bin/cpicalc.pl)

Challenges Facing Hospitals: Workplace Injuries Impact OR Staff

Key Takeaways:

- Hospital work-place injuries are common and employees, including OR staff, often experience injuries resulting in missed workdays[8,33,34]
- Job-related musculoskeletal pain and injuries experienced by OR staff and surgeons are common[9,10]
- Physical demands of the OR impact the rate of leaves of absence, turnover, and even early retirement for nurses and physicians[11-13]
- Maintaining postures required for holding surgical instrumentation, such as retractors, for extended periods of time greatly contributes to musculoskeletal pain and injuries of OR nurses and surgeons[14,15,18,35]
- Inconsistent retraction causes fluctuations in applied forces on soft tissues surrounding the surgical site, which may result in a risk of soft tissue damage or nerve injury[22]

OR Nurses and Surgeons Experience High Rates of Work-Related Pain and Injury

Hospital work-place injuries are common and may result in missed workdays; additionally, OR staff often work while injured or experiencing pain.

- According to the US Bureau of Labor Statistics, hospital employees suffer work-related injuries at nearly twice the national average rate for private industry as a whole; 48% of these injuries are due to overexertion or bodily reaction often resulting in sprains, strains, fractures, cuts, and punctures.[8]
- Among hospital units, OR staff—including nurses and aides—have some of the highest rates of injury resulting in days away from work, ranging from 12.5 to 15.7 injuries/100 FTEs.[33]
  - Up to 50%-75% of OR staff injuries, particularly from perioperative nurses, may go unreported.[34] Therefore, in actuality, the incidence rate of injury may be even greater.
  - Compared to other hospital units, OR staff are the most likely to work through their shifts while injured (10.1 to 17.6 injuries/100 full-time OR staff versus 2.1 to 15.6 injuries/100 full-time staff in other units).[33]

Job-related pain experienced by OR staff and surgeons may lead to increased rates of turnover and burn out.

- Work-related musculoskeletal disorders are common for OR nurses and surgeons:[9,10]
  - In a 2010 study of OR nurses, most (86%) experienced some type of musculoskeletal pain in a 12-month period; many reported needing to see a physician (39%) or take medical rest (25%) because of their symptoms.[9]
- For surgeons, musculoskeletal pain is a pressing concern:[10,11]
  - In a meta-analysis of >5,000 surgeons, 68% reported having generalized musculoskeletal pain; operating-related fatigue (71%) and stiffness (45%) were also common.[10]
  - A meta-analysis of >1,500 physicians (mainly surgeons) found that career prevalence of musculoskeletal injuries, including carpal tunnel syndrome, rotator cuff pathology, and degenerative spine diseases ranged from 9% to 18%.[11]

- Physical demands are a key contributor to rates of leaves of absence, turnover, and early retirement for nurses and physicians.[11,12]
  - 20% of nurses in a 2012 survey cited physical demands as a reason for leaving their jobs,13 and up to 11% of nurses report changing jobs specifically due to musculoskeletal injuries.[12]
  - Overall, 12% of physicians required a leave of absence, practice restriction/modification, or early retirement due to work-related musculoskeletal injuries.[11]

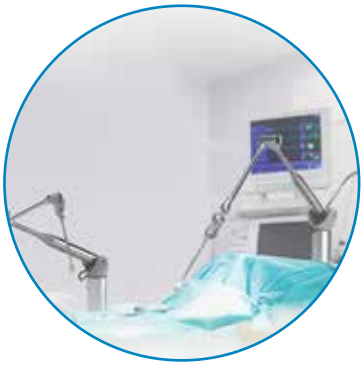
Among surgeons, musculoskeletal pain has been characterized as an "impending epidemic", which may result in practice restriction/modification, leaves of absence, burnout, medical treatment or surgery, or early retirement.[10,11]

Surgical Tasks Performed with Inappropriate Working Postures or for Long Periods of Time May Result in Musculoskeletal Disorders and Impact Employee Turnover

Physical demands of OR include standing, holding instrumentation, etc. for long periods of time.

- Inappropriate working postures may be a key factor in the development of musculoskeletal disorders; physical ergonomic risk factors need to be considered in order to mitigate the risk of injury.[14]
  - The high rate of musculoskeletal pain in the OR has been attributed to the cumulative effects of these risk factors, which include awkward positioning during surgical procedures and holding equipment, such as retractors and instruments, for long periods of time often totaling 5-8 hours per day.[15-17]
- Compared with other hospital physicians, surgeons report more severe physical strains on a daily basis.[35]
  - An observational study of surgeons and other hospital physicians at an academic medical center found that in an average workday, surgeons stand (4.5 hours vs 3.1 hours, P=0.004) and perform fine repetitive movements (80 minutes vs 3 minutes, P<0.001) for significantly longer periods of time compared with other hospital physicians.[35]
- A study examining the working postures of OR nurses using the validated Rapid Entire Body Assessment (REBA) method showed that inappropriate working postures during various activities put nurses at risk for development of musculoskeletal disorders.[18]
  - In particular, working postures during retraction were in need of drastic improvement, with 63% of nurses being at high or very high risk of developing musculoskeletal disorders.[18]
  - Nurses in all operating specialties evaluated were performing tasks with inappropriate working postures, with nurses in cardiac and gynecology ORs at greatest risk for development of musculoskeletal disorders.[18]

- Several additional studies further highlight the ergonomic risks to both surgeons and assistants of holding surgical instrumentation, such as retractors, endoscopes, and laparoscopes, which require intermittent adjustment throughout the procedure between static periods:
  - In a 2016 survey of laparoscopic surgeons, the majority (77%) reported physical complaints directly attributable to the use of laparoscopic instruments, primary in the upper extremities.[20]
  - A study evaluating ergonomic stress experienced by assistants during simulated laparoscopic procedures found that high-risk ergonomic postures were adopted during laparoscopic scope holding and retraction.1[9]
- Humans are not machines and may introduce variability in endurance level and ability to provide consistent hand-held retraction during the surgical procedure.
  - The quality of hand-held retraction is highly dependent on the skill and knowledge of the assistant holding the retractor(s).[21]
  - The ability to maintain a stable position during retraction depends on a variety of factors, including the patient's position, the assistant's endurance, and the retractor's design.[22]
  - Inconsistent retraction inevitably results from muscle fatigue of the assistant holding the retractor and/or regular positional correction of the retractor by the surgeon.[22,36]
- Inconsistent retraction leads to fluctuations in applied force, from too little retraction to excessive retraction, which may contribute to increased stress on surrounding tissues and, consequently, a greater risk of tissue damage.
  - Excessive retraction exerts considerable force on surrounding soft tissues and may cause damage and postoperative pain; a key complication associated with excessive or inappropriate retraction is nerve injury.[21-23]
  - Nerve injury is an underdiagnosed and underreported complication in knee, hip, and shoulder surgeries, estimated to occur in approximately 1% to 3% of said procedures.[22,37]
    - Incidence of nerve injuries may be substantially higher in other procedures; rates of nerve pain following lateral spinal procedures may be up to 75%.[38]



- Additionally, optimal performance during minimally invasive procedures may be compromised when instrument stability is dependent on human assistants.
  - Fatigue of camera-holding assistants may result in "camera shake", leading to the surgeon's loss of orientation, particularly with procedures utilizing 3D vision.[39]
  - Failure of camera-holding assistants to correct image rotation may result in distortion of the surgical field, which can lead to increased procedure time and increased risk of adverse effects.[40]
  - A study evaluating both novice and experienced laparoscopic surgeons found that as the image rotation increased from 0° to 90°, both time to completion of suturing tasks (P=0.004) and error rate (P=0.04) were significantly increased.[40]

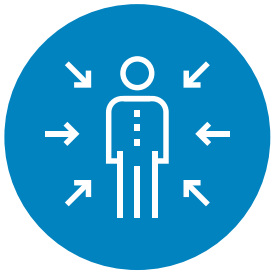
Despite the known ergonomic risks, solutions have been difficult to implement, in part because of a lack of surgical assistance equipment capable of adapting to unique patient geometries and time constraints of the OR.[10]

In 2011, 58,860 work-related injuries and illnesses caused US private hospital employees to miss work.[33] **Thousands more continue to work while injured,** potentially exacerbating injuries and **negatively affecting patient well-being.**[33]

86% of nurses say they frequently work with **musculoskeletal pain.**[9]

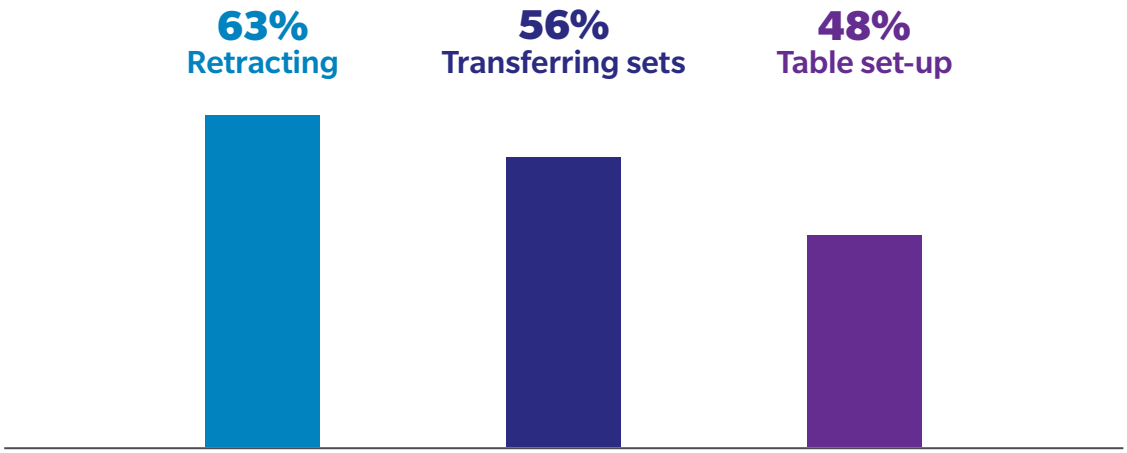
Work-related injuries and illness/100 FTE in 2011 (US).[33]

Rate of work-related injuries and illness is nearly **2x higher in hospitals vs. private industry as a whole.**[15]



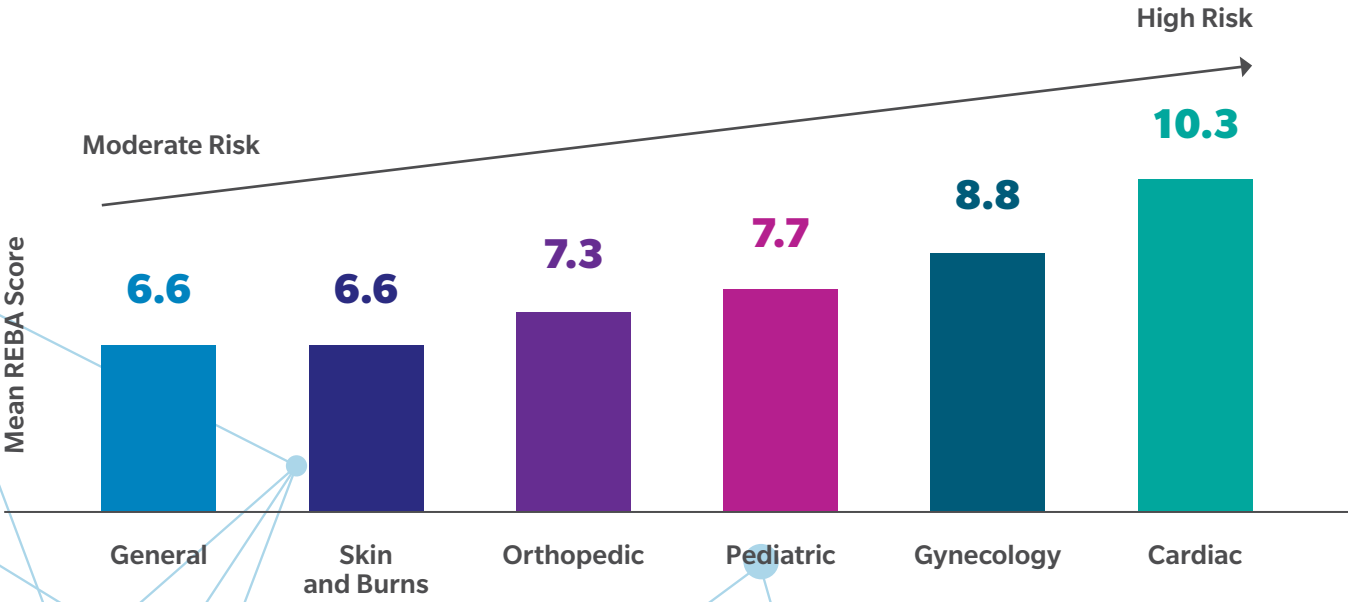
Nearly half these injuries are due to **overeaction or bodily reaction**[8]

Working postures during common job-related activities put OR nurses at risk for developing musculoskeletal disorders.[18]



Nurses with REBA high/very high risk level working postures (%)

OR nurses across operating specializes work with ergonomically risky postures.[18]



Challenges Facing Hospitals: Economic Impact of OR Staff Injuries is Substantial

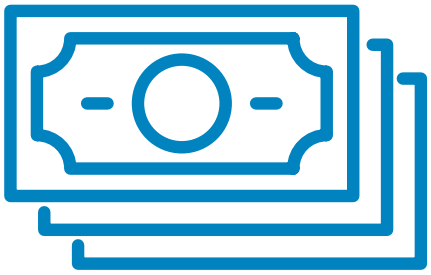
Key Takeaways:

- Direct costs of hospital employee work-related injuries include high-cost workers' compensation claims, which may cost the US healthcare system $2 billion annually[24]
- Indirect costs, often resulting from employee turnover, present substantial challenges for hospitals[24,41]
- Vacancies left by OR nurses and surgeons take considerable time to fill and result in sizeable costs to healthcare systems[25,26]

Hospital Work-Related Injuries Dramatically Increases Both Direct and Indirect Costs

The financial impact of hospital employee work-related injuries on the healthcare system is significant.

- Direct costs include lost wages and medical costs associated with workers' compensation claims, costs associated with absenteeism, including temporary staffing, backfilling, overtime, and additional sick days and healthcare visits.[24]
  - In a US survey of approximately 1,000 hospitals, workers' compensation claims to cover lost wages and medical costs were associated with a loss of $0.78 for every $100 of payroll; on a national scale, this translates to a total cost to the healthcare system of $2 billion annually.[24]
- Additionally, indirect costs—including costs associated with employee turnover, such as recruitment, hiring, and training of new employees, and loss of productivity and morale—are substantial.[24,41]
  - The number of surgical procedures is rising, but supply of OR staff, especially nurses, is falling.[32,42] The US Bureau of Labor Statistics estimates that >1 million registered nurses will be needed by 2022 to fill projected vacancies.[43]
    - The average time needed to recruit an experienced registered nurse is 81 days; OR nurses are the most difficult to recruit, with vacancies taking an average of 115 days to fill.
    - The estimated cost to replace nurses who leave the hospital ranged from $33,000 to $56,000 per nurse, resulting in an annual cost of $3.7 million to $6.1 million per hospital.
  - The financial impact of surgeon work-related injuries is not well-characterized, however, a study from 2015 estimates indicate that the annual burnout-attributable costs of surgeon turnover and reduced hours are approximately $1.4 billion and $300 million USD.[26]
    - At the organizational level, the annual burnout-attributable cost was estimated at approximately $10,000 per surgeon.[26]

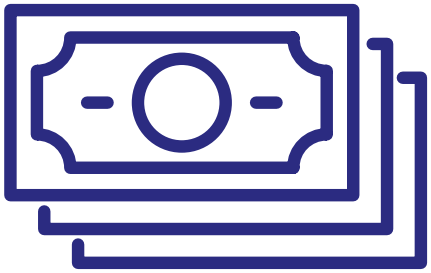


Direct costs include workers' compensation and **costs associated with absenteeism**[24]

Claims for workplace injuries are associated with a **direct total annual cost** to the healthcare system of **$2 billion**[24]

Additional indirect costs are related to **employee turnover** and training of new employees, as well as **loss of productivity and morale.**[24,41]

Estimated cost to **replace registered nurses** is between **$3.7 million to $6.1 million/hospital/year**[25]



Estimated burnout-attributable annual cost of surgeon turnover and reduced productivity is **~1.4 billion; at ~10,000/surgeon/year**[26]

Key Takeaways: The Value of WalterLorenz

- The WalterLorenz Arm is a bionic, electromechanical device enables steady retraction of tissue and surgical site optimization and may be used for tissue retraction in a number of surgical applications including shoulder arthroplasty, total & partial knee replacement, direct anterior and posterior hip arthroplasty, robotic-assisted total knee arthroplasty, maxillofacial, thoracic, foot and ankle, trauma, and spine.
- When used in the surgical theater, the WalterLorenz Arm was designed to streamline the OR workflow by providing controlled, consistent, and steady retractor placement; thereby, providing immediate support in the OR that is easy to use with minimal training required.
- The WalterLorenz Surgical Assist Arm is adaptable to the current OR workflow and works along with common OR instrumentation.
- Surgical instruments positioned with the WalterLorenz Arm are placed with 7-degrees of freedom similar to the range of motion of a human arm; the WalterLorenz Arm retracts tissue without obstructing the surgical field of view and gives surgeons complete control of retractor positioning.
- The WalterLorenz Arm can possibly spare human assistants the musculoskeletal pain and fatigue that may result from holding inappropriate working postures for extended periods of time.
- Overall, the WalterLorenz Surgical Arm provides OR staff and surgeons the support they need by offering a streamlined workflow and promoting efficiency, without some of the challenges associated with human retractor control.

In Summary:

- Factors such as OR team size and composition, turnover time, and reducing delays all influence the efficiency and workflow of the OR.[1-5] There is a delicate balance to optimizing these factors and reduce inefficiencies that impact OR staff, surgeons, and patients.[6]
- Surgical procedures often require surgeons and nurses to adopt postures that place them as risk for musculoskeletal pain and injuries.[9,10] Specifically, holding surgical instrumentation, such as retractors, greatly contributes to musculoskeletal pain and injury experienced by OR staff and surgeons; however, controlled, consistent, and steady retraction must be maintained during each surgical case in order to reduce the risk of stress on surrounding tissues and potential for soft tissue damage.[14,15,18,22,35]
- Work-related injuries are costly to hospitals both in direct costs of workers' compensation, but also indirect costs associated with OR nurse and surgeon turnover.[24,41]
- Hospitals should seek out technologies that are designed to promote OR efficiency and streamlined workflow while balancing the physical demands of the job that may result in risk of pain or injury to OR staff and surgeons.
- Additionally, indirect costs—including costs associated with employee turnover, such as recruitment, hiring, and training of new employees, and loss of productivity and morale—are substantial.[24,41]

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