

Oblique Lateral Lumbar Interbody Fusion (OLLIF)

Study Protocol, Results and Cost Analysis Graphs

Lower back pain is one of the most prevalent and expensive health care conditions in the western world. The standard treatment, interbody fusion, is an invasive procedure that requires stripping the muscles and soft tissue. This leads to blood loss and a long recovery time.

The Oblique Posterior Lateral Lumbar Fusion (OLLIF) is a surgical procedure designed for a minimally invasive spinal fusion. The OLLIF allows for fusion of the lumbar spine through a single 10-15mm incision, with faster surgery times and easier approach than any previous technique. This procedure is normally performed for patients that require a spinal fusion, but do not want the recovery time required in a traditional spinal fusion surgery.

There are also cost reductions associated with the OLLIF procedure. Based on a comparison of the results from 154 OLLIF patient results and 56 TLIF patient results there are significant cost reduction with the OLLIF. The minimally invasive approach of the OLLIF results in significantly less blood loss than the TLIF. It also results in less surgery time which greatly reduce costs. Depending on the level of the procedure, the surgery time cost reduction can exceed \$8,500.00. The patient spends less inpatient days creating a potential cost reduction of more than \$5,500.00 depending on the number of levels. The OLLIF can result in cost reductions in excess of \$14,000.00.

The cost reductions and faster recovery times associated with the OLLIF procedure make it an appealing alternative to the traditional open fusions available for the patient and insurance providers. This is evident in the included study results and cost analysis completed based on those results.

I look forward to speaking with you directly so I may further present the benefits of this advanced minimally invasive surgical procedure, the OLLIF.

Sincerely,

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Board Certified Neurosurgeon

Abstract and Key Words

BACKGROUND CONTEXT:

Lower Back pain is one of the most prevalent and expensive health conditions in the western world. The standard treatment; interbody fusion, is an invasive procedure that requires the stripping of muscles and soft tissue, leading to surgical morbidity. Current minimally invasive (MI) spinal fusions are technically demanding and suffer from technical limitations.

PURPOSE:

Oblique Lumbar Later Interbody Fusion (OLLIF) is a new technique for fusion of the lumbar spine that overcomes these complications. Outcome measures include patient demographics and reported outcomes, and surgical outcomes.

STUDY DESIGN/SETTING:

A level 3 retrospective cohort study

METHODS:

OLLIF's major innovation is to approach the disk through Kambin's triangle. Aided by bilateral fluoroscopy, Kambin's triangle can easily be located as a silent window with an electrophysiological probe. Discectomy is performed through a single access portal with 10mm diameter. After discectomy, disk space is packed with tricalcium phosphate soaked in autologous bone marrow, aspirated, and the cage is inserted. Finally, minimally invasive posterior fixation is performed.

RESULTS:

We present data from 69 consecutive OLLIF surgeries on 128 levels with a control group of 55 consecutive open Transformational Lumbar Interbody Fusions (TLIFs) on 125 levels. For a single level fusion OLLIF, mean surgery time is 69 minutes (min) and blood loss 29ml. Surgery time was approximately twice as fast as open TLIF (mean 135min) and blood loss is reduced by over 80% compared to TLIF (mean 355ml).

CONCLUSIONS:

OLLIF is a minimally invasive fusion that significantly reduces surgery times compared to open surgery.

OLLIF overcomes difficulties of traditional open fusions, making it a safe and technically less demanding surgery than open or minimally invasive TLIF.

Keywords

Operative Surgical Procedures; Minimally invasive; Spinal fusion; Lumbar spine; Disk disease; Interbody fusion; Spine surgery; Level 3 retrospective cohort study

Key Points

1. This study retrospectively assesses perioperative outcome data from Oblique Lateral Lumbar Interbody Fusion (OLLIF) patients and compares them to open TLIF patients performed by the same surgeon.
2. OLLIF significantly reduces surgery time, blood loss and hospital stay compared to open TLIF.
3. OLLIF is a novel technique that allows for fusion of the lumbar spine through a single incision, with faster surgery times and easier approach than previous techniques.
4. OLLIF is usually complimented with posterior minimally invasive instrumentation or fusion.

Mini Abstract/Précis

TLIF is an invasive procedure that may lead to higher surgical morbidity. OLLIF is a technique that helps reduce surgical complications associated with TLIF. OLLIF significantly reduced surgery time, blood loss and hospital stay compared to open TLIF therefore providing a safe and effective surgical option to open/minimally invasive TLIF.

Introduction

Low Back pain is one of the most prevalent and expensive health conditions in the Western world with up to 80% of all people suffering from it at some point during their life.^{1,2} It is the leading cause of activity-limitation for people under 45, one of the most common causes of health care utilization, and the third most common cause of surgical procedures in the United States.¹ In recent years the rate of disability due to low back pain has increased dramatically and consequently costs have skyrocketed; particularly in patients with disk disorders.^{2,3} In light of these data, improvements in surgical treatments of disk disorders could benefit hundreds of thousands of patients annually and contribute to lower health care costs.

As a treatment for disk disorders, Posterior Lumbar Interbody Fusion (PLIF) was developed in the 1950s and became the standard procedure to achieve interbody arthrodesis.⁴ Harms et al developed Transformational Lumbar Interbody Fusion (TLIF).⁵ TLIF has emerged as a popular alternative to PLIF because it allows for unilateral approach which leaves the contralateral laminae and facets available for posterior fusion. TLIF has been shown to cause less surgical morbidity and thus a quicker recovery than PLIF.^{6,7} However, during the approach for TLIF, muscles are still detached and denervated which may cause significant morbidity.⁸ To address these issues, minimally invasive (MI) TLIF has been developed.⁹ MI TLIF decreases blood loss and complication rates relative to open TLIF, but surgery times are similar or even longer than open TLIF.^{10,11} Post-operative recovery is also reduced in MI TLIF and long term outcomes are generally as good, but not better, than for open TLIF.^{10,12} MI TLIF still requires a fairly generous laminectomy and facetectomy so it is essentially a traditional open TLIF, in which the spine is accessed and directly visualized through smaller surgical corridor.^{9,13} This makes MI TLIF a technically challenging procedure that has not replaced open TLIF, even though it was developed almost a decade ago.¹³

Oblique Lateral Lumbar Interbody Fusion (OLLIF) is a new technique that allows for fusion of the lumbar spine through a single 10-15mm incision, with faster surgery times and easier approach than any previous technique. OLLIF eliminates the need for direct visual reference during the surgery with the help of electrophysiological monitoring.

OLLIF's major innovation is to perform spinal fusion via Kambin's triangle (**Figure 1**). Kambin's triangle has long been used as an access route to the disk.^{14, 15} It is made up of the exiting nerve (hypotenuse), the superior border of the caudal vertebra (base), and the traversing nerve root or the superior articular process (height).¹⁶ Because the triangle is an electrophysiologically silent window OLLIF requires no direct visualization. The approach is guided solely through electrophysiological monitoring and biplanar Fluoroscopy. In this article, we describe the technique and instrumentation used for OLLIF. We present perioperative outcome data from 69 OLLIF procedures and compare them to 55 open TLIFs done by the same surgeon.

Materials and Methods

Study Design

This was a retrospective case series including 69 OLLIF patients and 55 open TLIF controls. All procedures were done by the same surgeon as single surgeon procedures. The TLIF control group was selected from patients who underwent surgery before the surgeon started performing OLLIF to eliminate selection bias. All 124 procedures were performed in two Minnesota hospitals; Douglas County Hospital, 111 17th Ave E, Alexandria, MN and Riverview Health, 323 Minnesota St, Crookston, MN. All surgeries were performed between March 2012 and December 2013. The study size derives from the number of surgeries in this time period.

Data were collected in the clinic electronic medical record (EMR) and summarized in Microsoft Excel.

Mann-Whitney U-tests were utilized to test the null hypothesis that the OLLIF and TLIF groups have the same or identical mean distributions for age, BMI, blood loss, and the uncensored time duration

variables. All data analyses were performed using SPSS (IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.).

Outcome measures

Anesthesia/surgery times, blood loss and fluoroscopy times were recorded for all patients by clinic staff and entered into the EMR database immediately after surgery. Because no suction is used in OLLIF procedures, blood loss for the OLLIF group was measured by weighing sponges and subtracting dry weight. Routine follow-up was done within 3 months, 6 months and 9-12 months post-surgery.

The OLLIF procedure

Patient selection

Pre-operative imaging included MRI, x-ray of the lumbar spine with flexion and extension and in many cases a discogram and computerized tomography (CT). OLLIF is indicated for severe degenerative disk disease, listhesis, discogenic stenosis and disk re-herniation. With some experience, OLLIF can also correct for scoliosis and other deformities. All patients have gone through a full course of conservative therapy before being considered candidates for surgery. Patient surgical indications are listed in **Table 1**. OLLIF is easiest in levels L1-L4, because rib attachments obstruct the approach in the thoracic spine and for a L5-S1 fusion the approach is sometimes obstructed by sacral ala and iliac crest. The following anatomical factors, initially considered for our indication setting, were relative contraindications for OLLIF: bony obstruction, significant spinal canal stenosis, large facet hypertrophy, grade II listhesis and other gross deformities.

With some experience and modifications, OLLIF can still be performed for T12-L1 and L5-S1 fusions, or when some of the above counter indications are present. In our initial indication setting, a L5/S1 fusion was considered if the iliac crest was more than halfway towards the L5 vertebrae in the lateral X-Ray view. Toward the end of the collection period, and with more surgical experience, L5/S1 were more freely considered for OLLIF.

OR Setup

Patient is placed in prone position on operating table. To simplify the approach, the patient is tilted away from the surgeon by 3-5° until after the cage is inserted. Then, the patient is planed back into a true prone position. To enable quick readjustment, 3M Ioban (3M Center, St. Paul, MN) transparent plastic draping is used to help the surgeon get a good sense of the patient's positioning.

Next, bilateral fluoroscopy is set up. The endplates of the target level should line up well in lateral view. In the anterior-posterior (AP) view, the disk needs to be visible but not necessarily completely aligned, and the spinous process should be centered between the pedicles. Electrophysiological monitoring is set up on the major muscle groups and the skull. The somatosensory evoked potential (SSEP) and electromyogram (EMG) is checked and monitored throughout the surgery.

Marking

In the AP view the midline and each disk are marked. A vertical line showing the midpoint of each disk is marked in the lateral view. To find the incision point, the depth of the disk in the lateral view is measured and marked as a distance from the midline in the AP view to give a natural 45° angle to the patient's back for approach; as illustrated in **Figure 2**. Usually the incision is placed 10-13cm from the midline. Multiple levels can be approached through the same incision by shifting the skin or approaching the disk at a slight angle.

Approach

Aided by Fluoroscopy, an electrode is inserted through the incision, traverses the retroperitoneal space and pierces the Iliopsoas fascia bluntly. To locate the silent window in Kambin's triangle, the electrode is stimulated at 3mA. In some cases, especially when Scoliosis or listhesis is present, the disk can be approached anterior to the nerve root, not actually passing through Kambin's triangle. This enables the surgeon to place the cage more strategically to achieve certain types of correction. Once contact with the disk is made, the electrode is stimulated at 4mA to verify there is no contact with the nerve root.¹⁷

Four of 4 twitches (no paralytics) is required for acceptance of the electrophysiological data. Once a silent window is found, the sleeve is pushed down over the electrode. The electrode is removed and a K-wire inserted past the midline into the disk. The sleeve is removed and a dilator introduced over the K-wire. While electrophysiological monitoring is continued, the dilator is entered with a careful circular motion, gently dilating the tissue. Often, a visible increase in foraminal size is observed at this point, which aids in protection of the nerve-root. Once the dilator is entered into the disk space, the access portal is delivered over it and tapped into the disk until it is medial to the pedicle in the AP view and inside the disk space by about 1/2cm in the lateral view. The final positioning of the access portal under bilateral fluoroscopy can be seen in **Figure 3**. The Zeus-O instrumentation system, manufactured by Amendia, Inc. (1755 West Oak Pkwy, Marietta, GA) as displayed in **Figure 4**, was used.

Discectomy and Cage placement

Disk material is removed first with a drill and then with a rotating cutter, ring curette and long pituitary, all delivered through the access portal. The endplates are prepared with serial dilation of the rotating curette. Tactile feedback from the curette indicates when the endplates are reached. It is important to ensure the endplates are free. Light violation of the endplates is acceptable and slight bleeding is not uncommon at this point. Next, the disk space is packed with tricalcium phosphate (Berkeley Advanced Biomaterials Inc., 901 Grayson St., Berkeley, CA) soaked in autologous bone marrow aspirate drawn from a Jamshidi needle in one of the pedicles.

A K-wire is placed and the access portal removed. At this stage cage width and height can be determined using a trial spacer. However with some experience the cage dimensions can also be determined during discectomy through tactile feedback from the rotating cutter, which has markings that indicate how wide the blades are spread.

Next, the cage (**Figure 5**, PEEK Zeus-O cage manufactured by Amendia) is inserted over the K-wire aided by fluoroscopy as seen in **Figure 6**. Its conical shape assures it makes its way through muscle fascia and

gently pushes the nerve root out of the way. For easier entry the cage can be rotated by 90° during approach and derotated once the tip has entered the disk space. With mallet taps the cage is entered until 1/3 of the cage is past the midline. Some electrophysiological activity is not unusual during cage entry. However all activity subsides once the cage is placed because the cage increases pedicle distance and causes indirect foraminotomy. Fluoroscopic image of completed cage entry in a two level fusion is shown in **Figure 7**.

Posterior Pedicle Screw Fixation

After cage placement, all patients undergo percutaneous posterior pedicle screw fixation. Savannah-T posterior instruments and high top screws manufactured by Amendia were used. The technique is similar to what has been described by Foley in 2001, but the technique was modified to allow for posterolateral fusion in addition to interbody fusion.¹⁸ Jamshidi needles have already been placed in one level at the beginning of the surgery to allow tricalcium phosphate to be saturated with bone marrow aspirate. Once the cage is inserted, all pedicles are tapped with Jamshidi needles that are stimulated up to 30mA to assure there is no contact to neural structure. All stimulation results above 18mA were accepted. It is necessary to ensure all Jamshidi needles are positioned correctly because repositioning is easiest at this point. K-wires are then placed through the Jamshidi needles, and once the positioning of all K-wires is confirmed, the AP fluoroscopic arm is removed to ease screw placement.

An osteotome with a groove is slid down the K-wire and the facets are bare boned aided by lateral fluoroscopy as illustrated in **Figure 8**. A small amount of dry tricalcium phosphate is placed in the just created space on the facets. To complete the surgery, the screws are inserted and the rod is placed as described by Foley. A fluoroscopic image of a completed two level OLLIF with posterior fixation is shown in **Figure 9**.

Results

Summary statistics for the two study groups are displayed in **Table 2**. There were no significant differences between the groups in either BMI or age. The only exception was that OLLIF 3 level patients were significantly older than their counterparts in the TLIF comparison group.

Perioperative outcomes are shown in **Table 3**. In all groups, OLLIF significantly reduced surgery times, blood loss and hospital stay compared to TLIF. In the 1 level group, mean hospital stay was reduced 1.6-fold, mean surgery time was reduced almost 2-fold, and mean blood loss was reduced 12-fold. There was one exception in that there was no difference between the two groups in the length of hospital stay in the 3 level patient groups. Fluoroscopy times were significantly longer (4.6-fold) in the OLLIF group (**Table 3**).

Additionally, OLLIF was a straightforward procedure to learn. **Figure 10** demonstrates how the mean surgery time for 10 successive OLLIFs dropped rapidly with experience. After operating on approximately 40 levels, the study surgeon came close to halving OR times for a single level OLLIF compared to his first surgeries.

Discussion

A systematic review of studies on MI TLIF/PLIF by Goldstein et al. found that single level surgery time for the MI fusions were not significantly different from their open equivalents.¹⁰ Surgery times for single level MI TLIF/PLIF in Goldstein's meta-analysis ranged from 104 to 390 minutes. This is much longer than our single level OLLIF cohort where surgery times ranged from 33 to 227 minutes. Goldstein et al. additionally reported blood loss ranging from 51ml to 496ml in the MI TLIF/PLIF subjects which is also higher than the 5ml to 300ml reported in our single level OLLIF group.¹⁰

OLLIF is the first spinal fusion that can be completed through a single 10mm incision. Current MI TLIF methods require an incision of 20mm or larger.⁹ During approach for MI TLIF muscles and soft tissue are

stripped from the surgical corridor and a facet is removed, which exposes the patient to surgical morbidity.^{8,9} OLLIF relies entirely on dilation and does not require facet removal. Whether this leads to lower rates of adjacent level disorder is currently under study.

In TLIF fusions, tricalcium phosphate is rarely packed into the disk space because of the risk of extrusion onto neural structure. OLLIF allows the surgeon to freely pack the disk space with tricalcium phosphate or biologic because the opening in the disk space is small and is essentially blocked by the cage. We hypothesize that this leads to higher fusion rates and are currently collecting data to investigate this. Due to the conical shape of the Zeus-O cage (as illustrated in **Figure 5**) we were consistently able to place cages approximately 3-4mm larger than during similar TLIF procedures. This creates considerable opening of the foramen and even spinal canal where disk herniation causes stenosis. Through the positioning of the cage and choosing side of entry it has even been possible to correct for listhesis and scoliosis.

This study is limited because it is a retrospective study. Using a retrospective patient cohort for comparison biases the data because clinical practices change over time. However the data on perioperative measures such as blood loss and OR time was collected almost completely and clearly shows that OLLIF improves on TLIF. Due to the magnitude of this change, it is unlikely to be just a side effect of the study design or this particular surgeon's skill. Therefore, OLLIF justifies further study as it has the potential to significantly improve the outcomes of patients with lumbar fusions.

This report describes OLLIF as the first MI fusion that is faster than open surgery. Data from 69 consecutive OLLIF surgeries and a control group of 55 consecutive open TLIFs suggest that OLLIF overcomes difficulties of traditional open fusions, thereby making it a safe and technically less challenging surgery than open or minimally invasive TLIF.

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Figure 1: Kambin's Triangle and surrounding anatomy

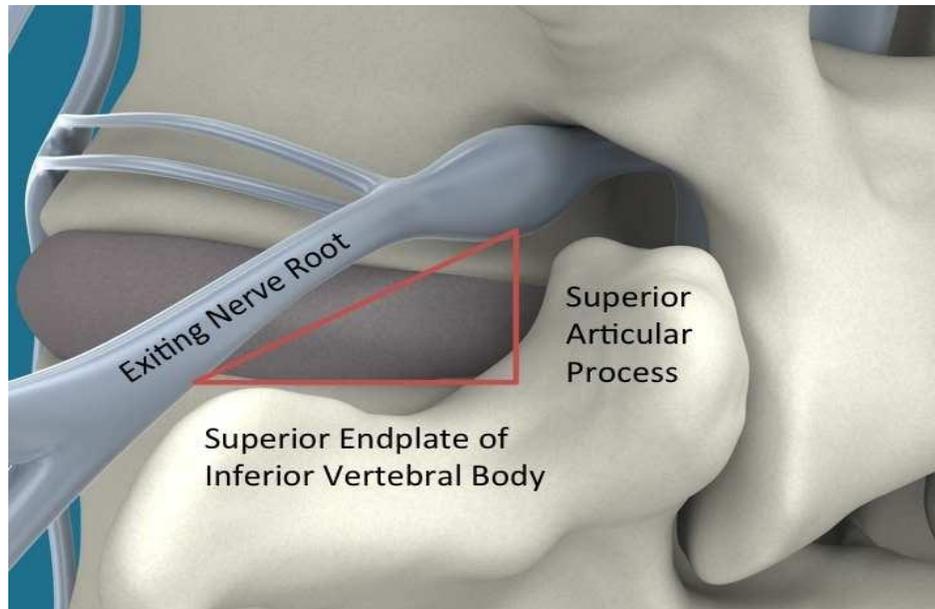


Figure 2: The incision point is chosen to give a 45° angle for approach to the spine

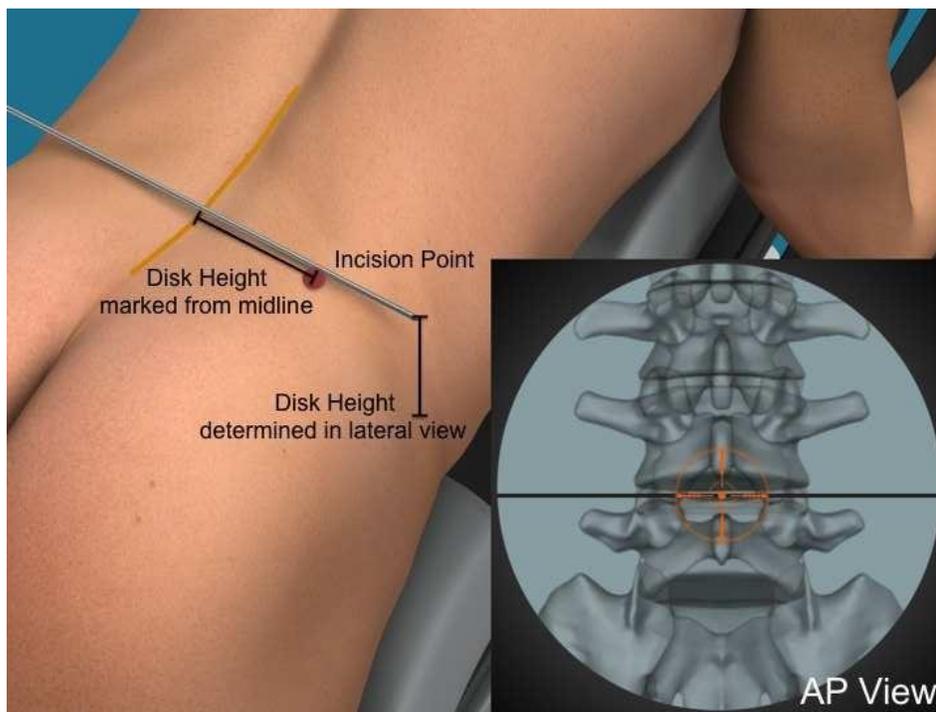


Figure 3: Fluoroscopic view of the Access portal on the spine (a) Lateral (b) AP



a.



b.

Figure 4: Instrumentation used for OLLIF, left to right: Probe, K-Wire, Dilator, Access Portal, Drill, Rotating Cutter, Disk Cutter, Pituitary, Cage Inserter

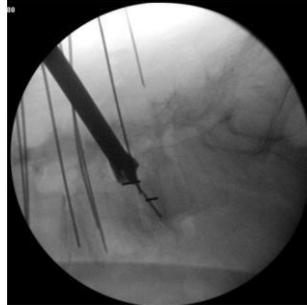


Probe, K-Wire, Dilator, Access Portal, Drill, Rotating Cutter, Disk Cutter, Pituitary, Cage Inserter

Figure 5: PEEK Zeus-O cage with bullet nosed tip



Figure 6: Fluoroscopic view of the cage being inserted (a) Lateral (b) AP

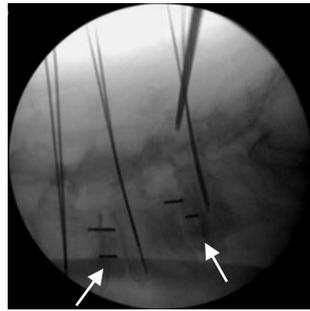


a.

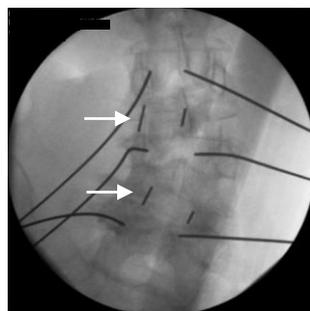


b.

Figure 7: Completed 2 level OLLIF with cages marked by arrows, K-wires for fixation are also visible (a) Lateral (b) AP



a.



b.

Figure 8: Lateral view of the Osteotome during facette bareboning

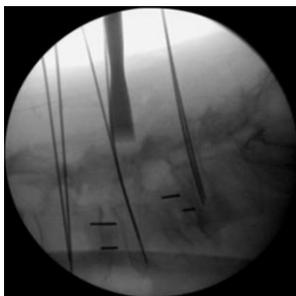


Figure 9: Lateral view of a completed 2-level OLLIF with posterior fixation

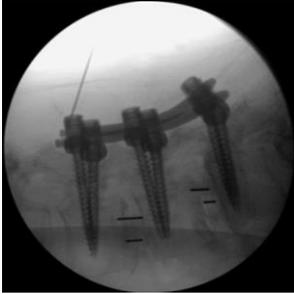


Figure 10: The surgeon's learning curve. Values are displayed as mean \pm SD of 10 successive single level OLLIF surgeries

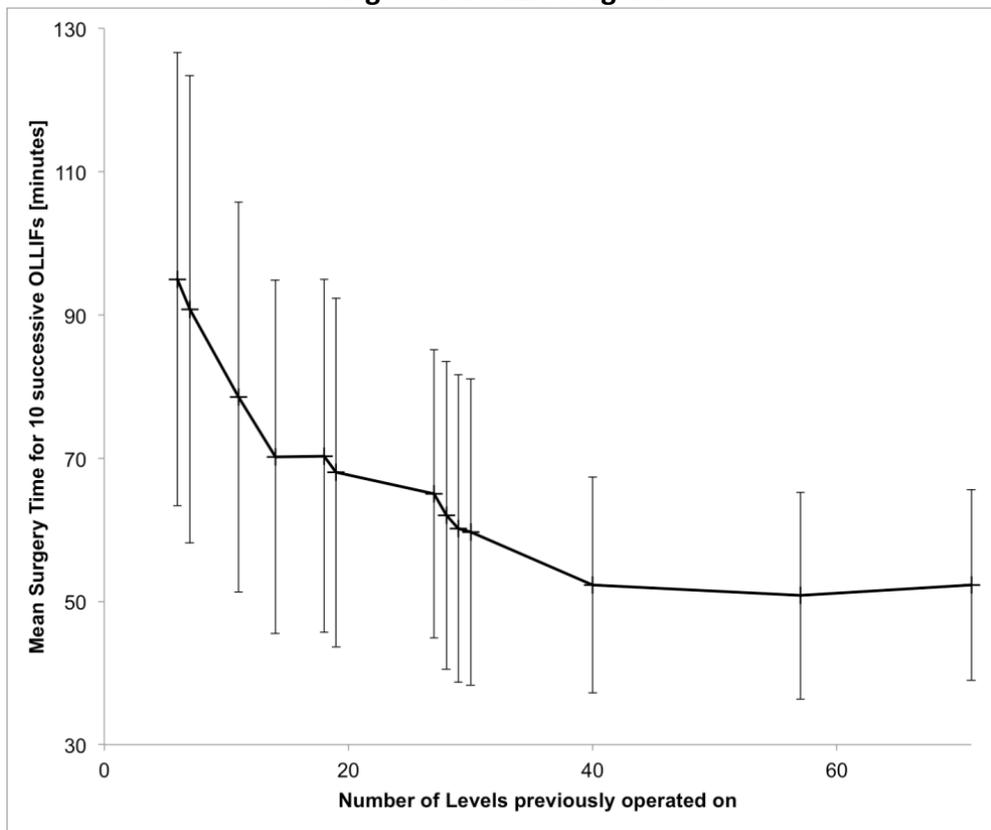


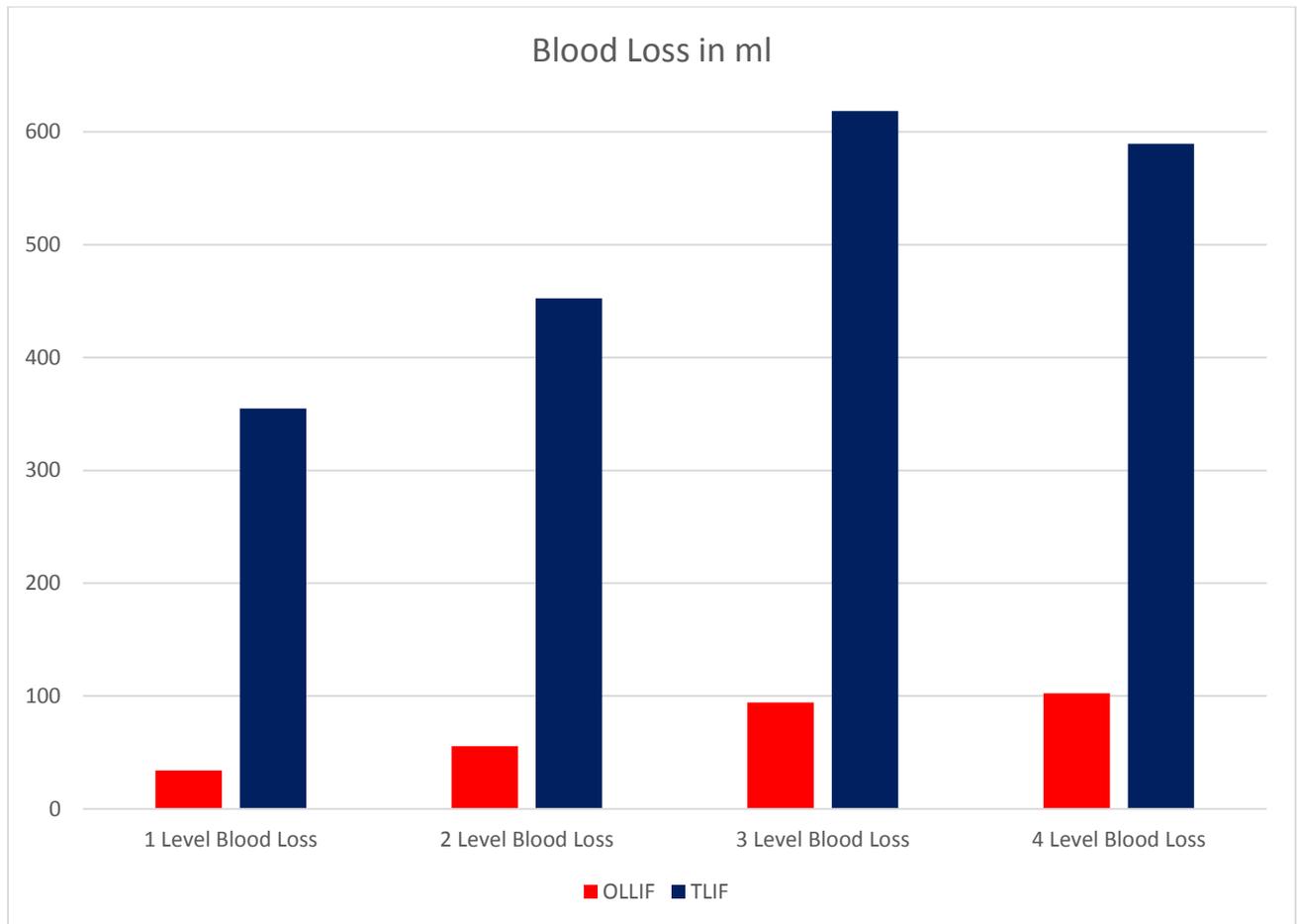
Table 2: Mean summary statistics of the study groups.

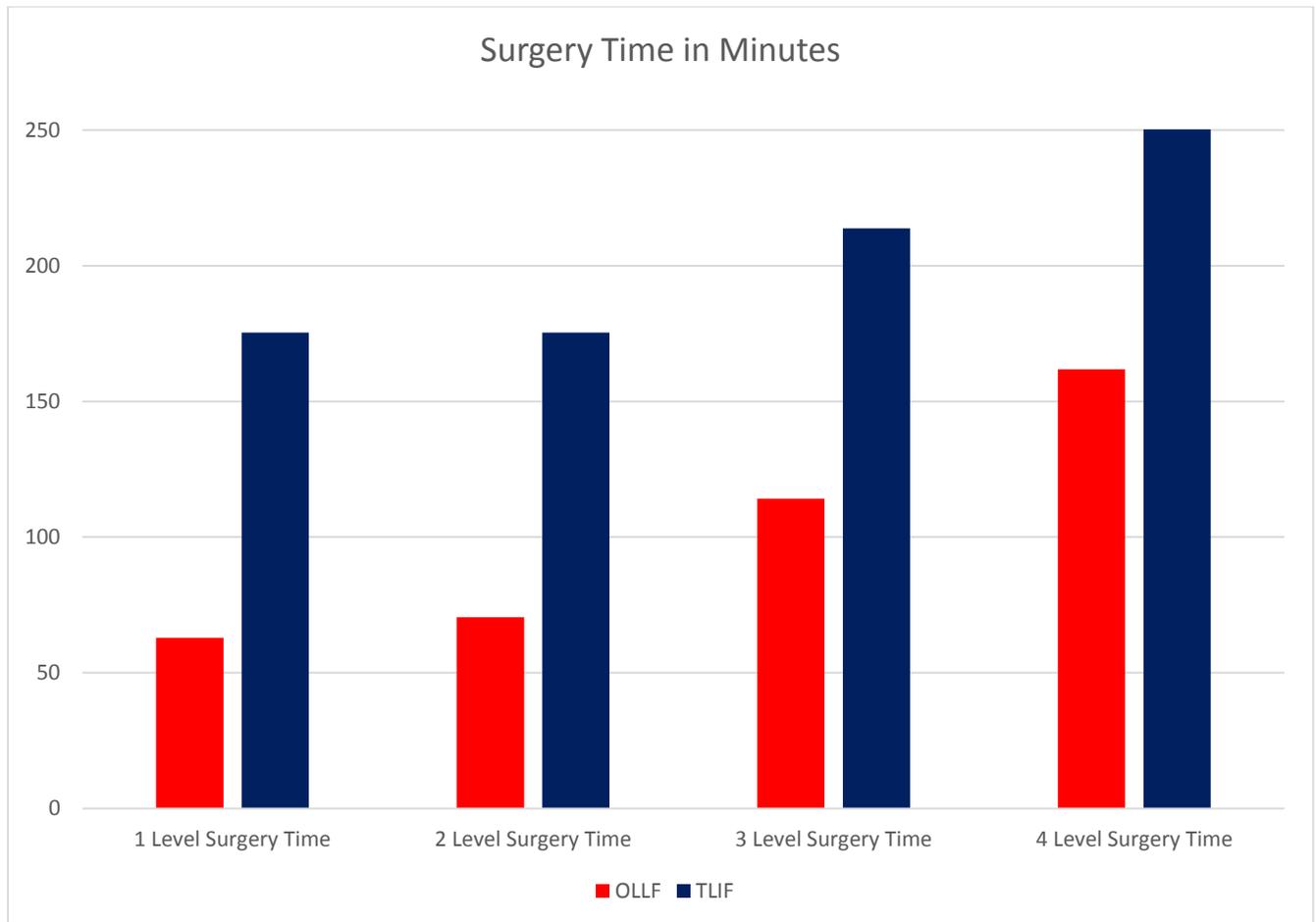
1 Level	OLLIF	TLIF	p value
Number	28	9	-
Age	56.1±15.2	64.1±20.9	0.226
BMI	29.5±5.8	31.0±4.8	0.541
2 Level	OLLIF	TLIF	p value
Number	24	19	-
Age	59.0±18.5	57.3±15.4	0.797
BMI	30.5±4.8	30.8±6.5	0.973
3 Level	OLLIF	TLIF	p value
Number	12	14	-
Age	68.7±11.7	58.3±8.7	0.023 **
BMI	30.9±8.4	35.4±6.3	0.160
4 Level	OLLIF	TLIF	p value
Number	4	9	-
Age	63.0±15.5	68.8±17.6	0.604
BMI	30.0±8.3	30.6±8.2	0.625

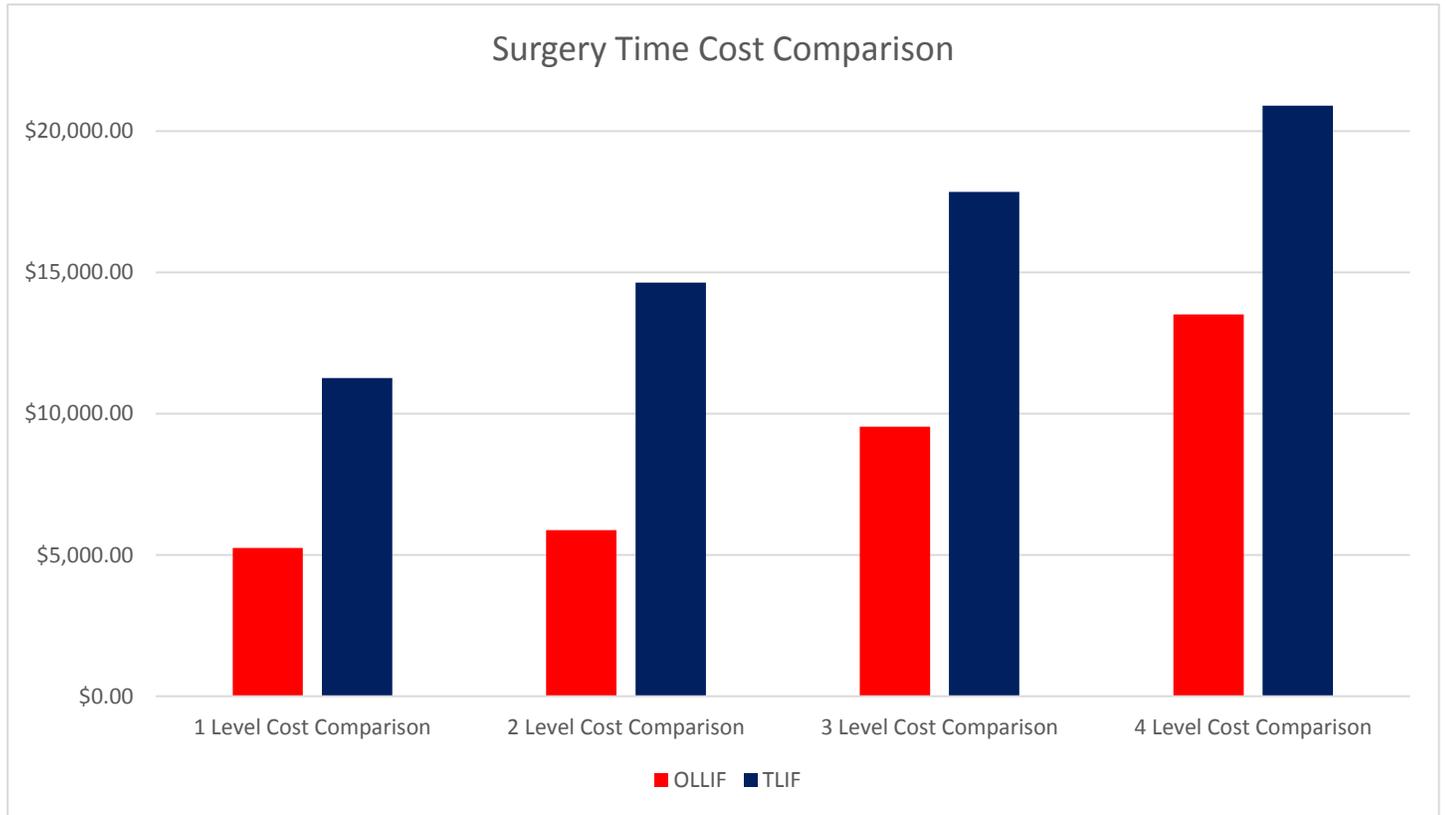
** Difference Significant at p<0.05

Table 3: Mean perioperative outcomes of the study groups

1 Level	OLLIF	TLIF	p value
Blood Loss (ml)	29.4±17.2	355.0±131.5	<0.001
Surgery Time (min)	69.2±29.4	134.9±21.7	<0.001
Fluoro (seconds)	201.8±73.2	43.8±29.9	<0.001
Days to discharge	2.6±1.7	4.2±1.2	0.001
2 Level	OLLIF	TLIF	p value
Blood Loss (ml)	76.7±78.4	452.6±327.6	<0.001
Surgery Time (min)	107.1±42.0	175.3±39.3	<0.001
Fluoro (seconds)	247.4±79.4	65.1±57.3	<0.001
Days to discharge	3.3±1.1	5.8±6.5	0.010
3 Level	OLLIF	TLIF	p value
Blood Loss (ml)	69.3±57.6	618.6±353.9	<0.001
Surgery Time (min)	136.6±42.9	213.7±40.5	<0.001
Fluoro (seconds)	455.5±234.9	100.5±106.9	<0.001
Days to discharge	4.5±2.2	4.3±1.3	0.940
4 Level	OLLIF	TLIF	p value
Blood Loss (ml)	125.0±66.1	589.4±255.3	0.009
Surgery Time (min)	176.0±25.8	250.2±73.6	0.020
Fluoro (seconds)	524.3±243.3	88.2±75.1	0.006
Days to discharge	4.0±0.0	6.7±1.6	0.011

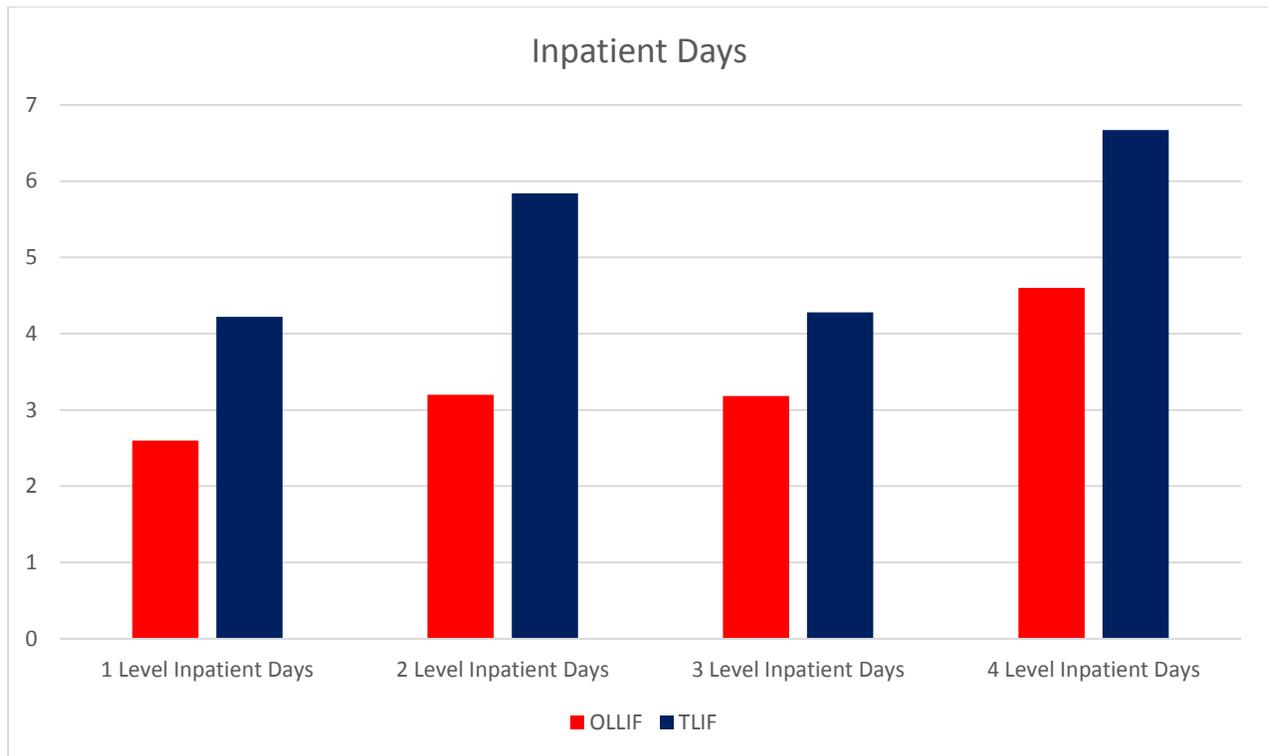


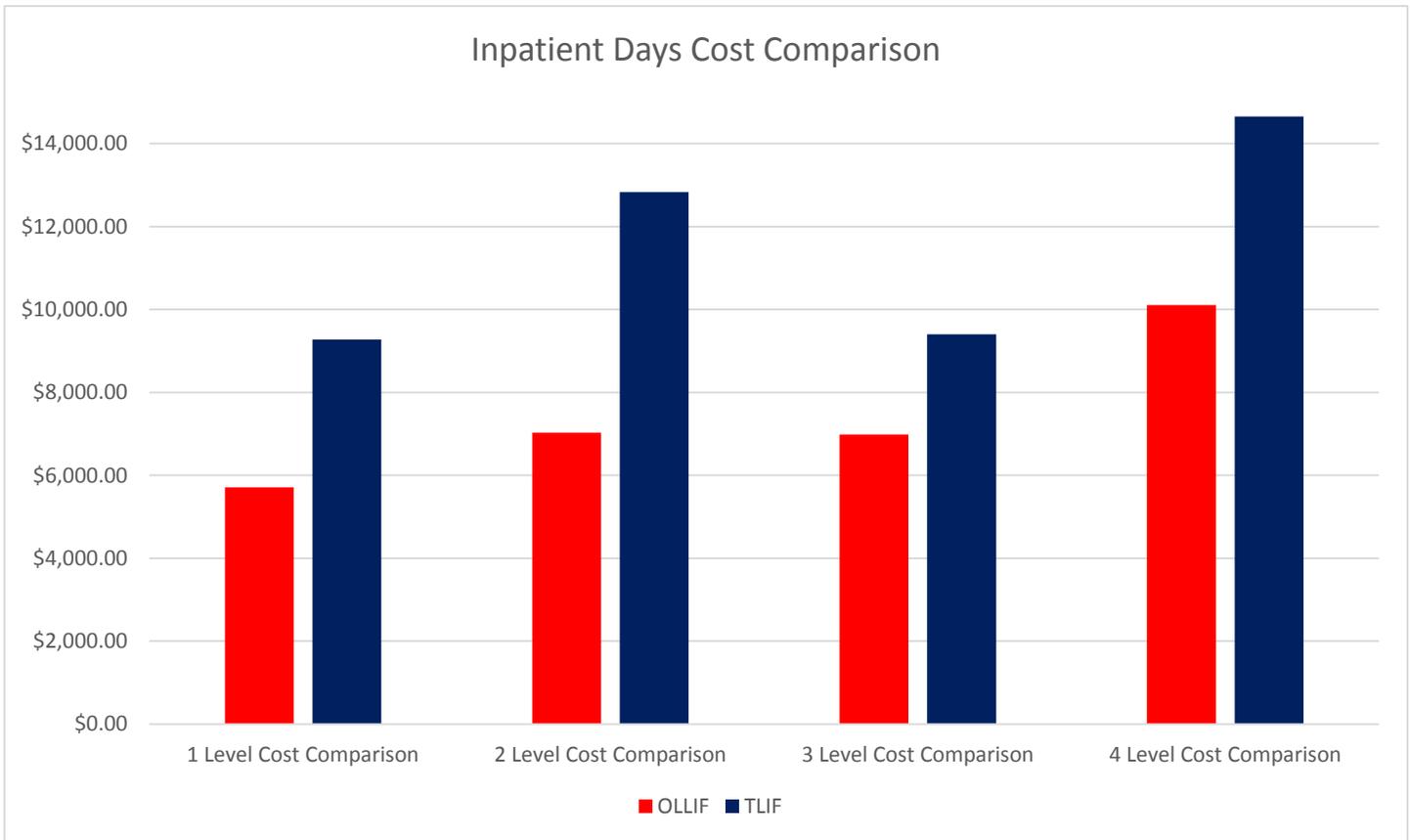




U.S. average cost per OR minute is determined by using \$62/ OR minute (see citation below), subsequently then applying and compounding the U.S. Bureau of Labor Statistics "Medical Care Indexation" from years 2006-2014.

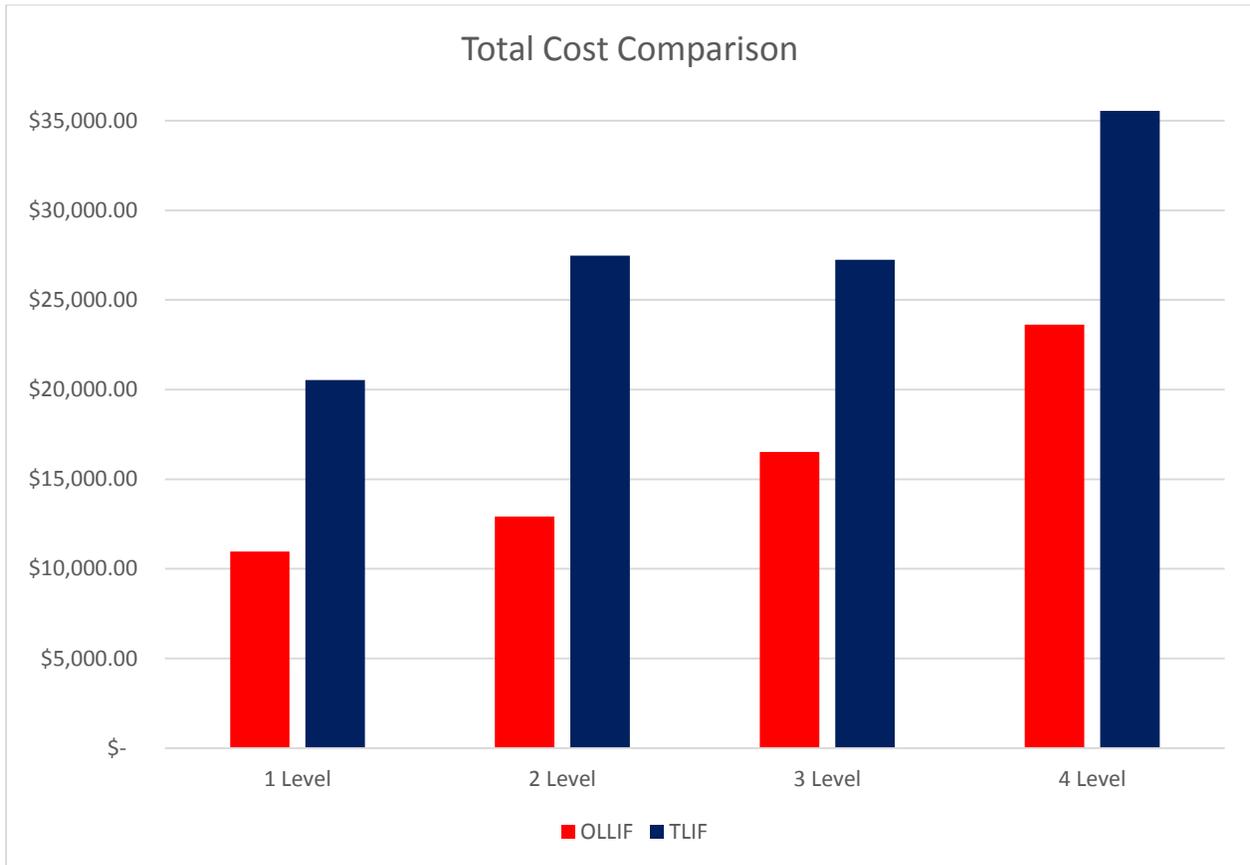
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U.S. average cost per inpatient day is determined by using \$2,090 (see citation below), subsequently then applying and compounding the U.S. Bureau of Labor Statistics "Medical Care Indexation" from years 2013-2014.

American Hospital Association. (2013, January 1). Hospital Adjusted Expenses per Inpatient Day. Retrieved January 30, 2014, from <http://kff.org/other/state-indicator/expenses-per-inpatient-day/>

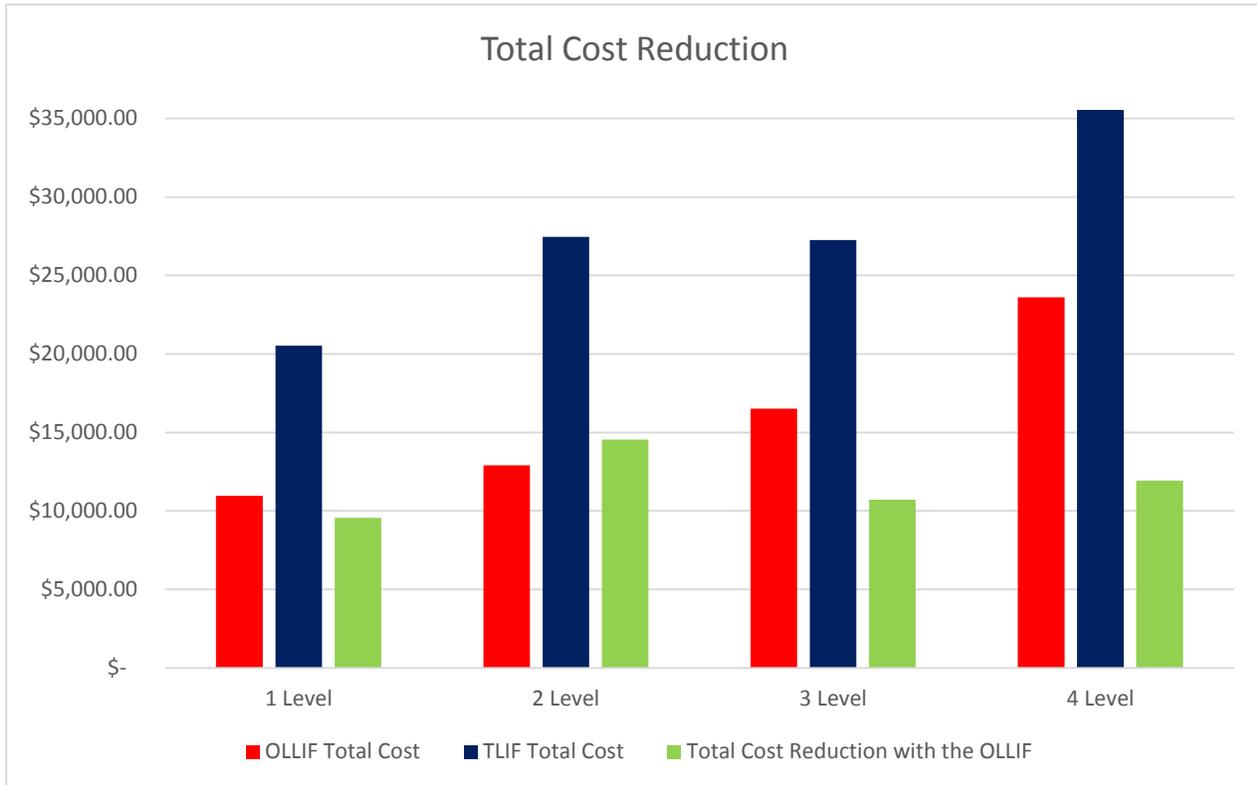


U.S. average cost per OR minute is determined by using \$62/ OR minute (see citation below), subsequently then applying and compounding the U.S. Bureau of Labor Statistics "Medical Care Indexation" from years 2006-2014.

Macario MD MBA, A. (2010). What Does One Minute of Operating Room Time Cost. *Journal of Clinical Anesthesia*, 210(22), 233-236. Retrieved January 30, 2015, from <http://ether.stanford.edu/asc/documents/management2.pdf>

U.S. average cost per inpatient day is determined by using \$2,090 (see citation below), subsequently then applying and compounding the U.S. Bureau of Labor Statistics "Medical Care Indexation" from years 2013-2014.

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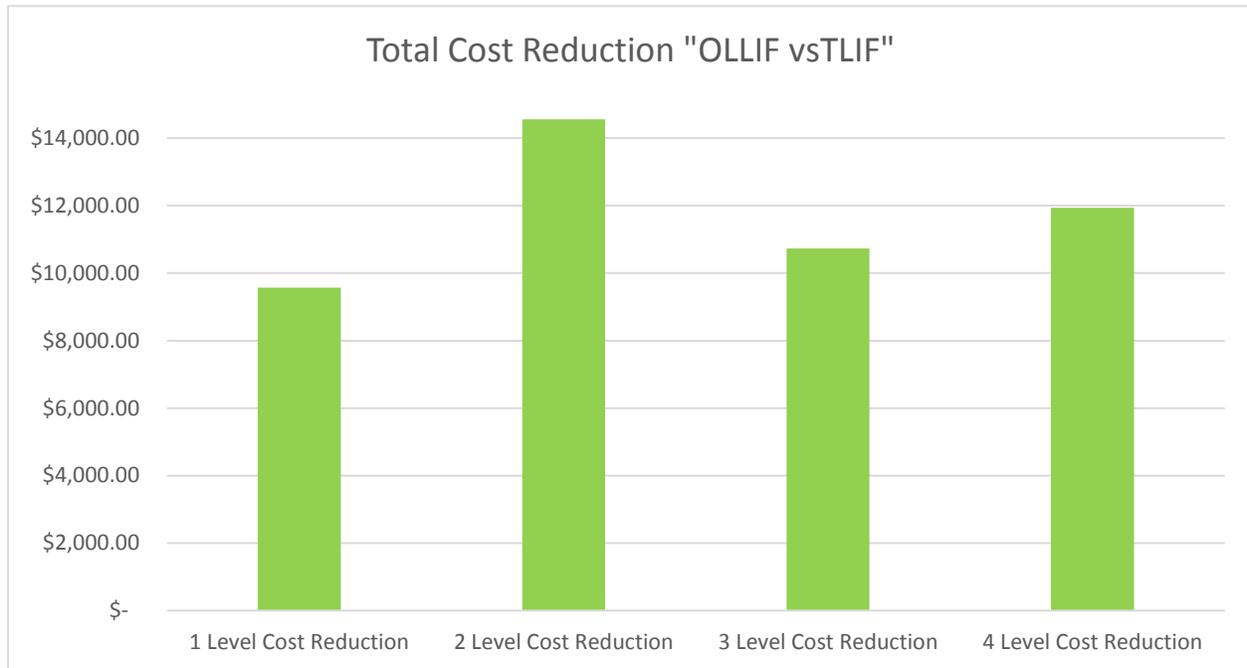


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