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A COMPARATIVE STUDY OF PEDICLE SCREW FIXATION IN DORSOLUMBAR SPINE BY FREEHAND VERSUS IMAGE-ASSISTED TECHNIQUE

By

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ABSTRACT

Background: Pedicle screw instrumentation has been used to stabilize the thoracolumbar spine for several decades. Although pedicle screws are originally placed via a freehand technique, there has been a movement in favor of pedicle screw placement with the aid of imaging.

Objective: To evaluate the safety and accuracy of pedicle screws placement with a freehand technique versus image-assisted technique.

Patients and methods: Patients of this study were divided into two groups: Free-hand group (group I). 18 patients and 108 screws and image assisted (group II) 32 patients and 264 screws). There were mainly for spondylolisthesis, fractures and deformity from March 2019 to November 2020 at Al-Azhar University Hospitals. Incidence and extent of cortical breach by misplaced pedicle screw was determined by a review of postoperative computed tomography (CT) images.

Results: A total of 50 patients received 372 free-hand and image assisted placed pedicle screws in the thoracic and lumbar spine. In free hand technique, a total of 8 screws (3.7%) were identified as breaching the pedicle laterally in 4 patients, and 4 screws (4.4%) breaching medially in 2 patients. In image assisted technique, a total of 14 screws (5.3%) were identified as breaching the pedicle laterally in 3 patients and 2 screws (0.75%) breaching medially in one patient. Upper thoracic spine was the most frequent location of screw breach (10.8%). The accuracy rate in our work was 89%% in the free-hand group compared to 94% in the image assisted technique group ($p<0.01$).

Conclusion: Freehand technique was as good as the image-assisted technique in comparison to safety and accuracy, using both techniques together this can result in high accuracy and efficacy that can reach up to 100%.

Key words: Free hand; Image assisted, Pedicle screw; Thoracic; Lumbar; Accuracy; Safety.

INTRODUCTION

The free-hand technique is for placement of pedicle instrumentation which relies completely on the use of visible as well as palpable anatomic landmarks for accurate pedicle screw placement, It is dependent on a clear exposition and identification of the posterior elements' bony landmarks, including the lateral border of the pars interarticularis, the entire transverse process and the caudal and cephalad facet joints *(Karapinar et al., 2012).* Pedicle

screw instrumentation has been used to stabilize the thoracolumbar spine for several decades. Although pedicle screws were originally placed via a freehand technique, there has been a movement in favor of pedicle screw placement with the aid of imaging. Imaging has the benefit of increased visualization of a pedicle's trajectory, but can result in increased morbidity associated with radiation exposure, increased time expenditure, and possible workflow interruption *(Agarwal et al., 2010).*

Pedicle screw fixation with rod constructs has attained global acceptance for stable spine fixation, A variety of techniques have been described in modern literature with free hand techniques having the unique advantage of being universally applicable, especially in the developing world with a dearth of equipment *(Lee et al., 2014).*

Freehand pedicle screw placement in the lumbar spine has enjoyed wide acceptance, but screw placement in the thoracic spine is more challenging due to the critical regional neurovascular anatomy and the narrow pedicular corridor mandating higher accuracy and precision *(Mattei and Milano, et al., 2011).*

The free hand technique has many advantages as it is not associated with radiation exposure, save time, prevents repeated interruption during surgery, and save money as the image assisted technique is of expensive technology *(Gang et al., 2012).*

All these advantages of free hand technique have the potential risk for permanent neurological deficits if pedicle screw mispositioned due to the critical regional neurovascular anatomy, and the narrow pedicular corridor mandating higher accuracy and precision *(Fennell et al., 2014).*

Assistive techniques were designed to decrease the breach rate and improve pedicle screw placement accuracy. However, it is unclear whether assistive technologies actually decrease cortical breach and improve outcomes when compared to free-hand techniques *(Laine et al., 2014).*

This study aimed to evaluate the safety and accuracy of pedicle screws placement with a freehand technique versus image-assisted technique.

PATIENTS AND METHODS

This was a prospective and retrospective study that was conducted on 50 patients with spinal pathologies, i.e, fractures, spondylolisthesis and deformity from March 2019 to November 2020 at Al-Azhar University Hospitals.

One hundred and eight pedicle screws were implanted in 18 patients (8 males and 10 females) using the freehand technique (group I), and 264 screws were implanted in 32 patients (13 males and 19 females) using the image assisted technique (group II).

Each patient was evaluated clinically, radiologically, and by other preoperative laboratory investigations to confirm fitness for general anesthesia.

Clinical evaluation:

Personal history included name, age, sex, occupation, address and special habits. History of trauma included: site, mode, time elapsed till presentation and severity. Neurological disorders included

sensory, motor and sphincteric disorders. History of chest, cardiac or general health problems that may hinder anesthesia.

Examination: General examination included evaluation of hemodynamic state of the patient (Pulse, blood pressure, temperature and respiratory rate). Head, chest and abdomen for life threatening injuries, Examination of extremities for associated injuries.

Spine examination included inspection of the back and other related regions, palpation of the spine, evaluation of deformity especially in old cases, and Sensory examination: Superficial sensation included pain, touch, temperature and perianal sensation. Deep sensation included: Joint sensation, sense of joint motion, sense of position and deep pressure sense.

Motor examination included muscle power, reflexes: (superficial and deep reflexes).

Radiological evaluation: Plain X- ray, CT and MRI.

After hospital admission, investigations were done to the patient who was instructed not to sit in bed. Antithrombotic treatment was started. No catheterization was used, Oral analgesics administrated with mild pain and parental analgesics with severe pain and poly trauma patients were administrated. The surgical procedure and postoperative management were discussed with patient and his relative, and the surgeon answered any question the patient had in mind about the operation.

Preoperative preparation and positioning:

All of the patients were given prophylactic antibiotic (3rd generation Cephalosporin) 1g before induction of anesthesia. The patients were positioned prone, under general anesthesia on a radiolucent table with a small towel under chest of the patient with hyper extension of the leg.

Operative techniques:

1. Incision and Exposure.

The spine was exposed to the tips of the transverse processes bilaterally, staying strictly subperiosteal to reduce bleeding. The facet joints were thoroughly cleaned of soft tissue. With an osteotome, the inferior 3–5 mm of the inferior facet and scrape the cartilage on top of the superior facet were removed to enhance the intra-articular arthrodesis.

2. The Cortical Burring of Starting Point.

Lumbosacral spine:The entry point was in the intersection between a line that passes just laterally to the inferior articular process and a line which bisects the transverse process. At S1, the entry point was at the infero-lateral margin of the basis of the superior articular process of the sacrum.

In the lower thoracic spine: The starting point was located at the junction of a vertical line which passed along the lateral boundary of the “pars articularis” and a transverse line dividing the transverse process in its half process and a transverse line along the superior border of the transverse process.

In mid-thoracic spine: the starting point began to move medially. At T7-T9, the starting point is the most medial, being located along a vertical line just lateral to the midpoint of the superior articular process and a transverse line along the superior border of the transverse process.

In upper thoracic spine: the starting point for screw insertion moved back more laterally. At T1-T2, the starting point was located at the intersection of a vertical line along the lateral border of the pars interarticularis and a transverse line bisecting the transverse process.

3. Gearshift Probing.

The gearshift (2 mm blunt-tipped, slightly-curved pedicle finder) was placed in the base of the pedicle searching for a cancellous “soft spot” indicating entrance to the pedicle. After inserting the tip , approximately 15–20 mm (to beyond the medially based spinal canal), the gearshift was removed and the tip turned to face medially. The tip was carefully placed into the base of the hole. Bone was felt the entire length of the pedicle and body.

4. Palpation and Pedicle Length Measurement.

Once the pedicle seeker was removed, the tract was visualized to make sure that only blood was coming out and not cerebrospinal fluid (CSF). The amount of blood extruding from the pedicle hole was noticed as excessive and/or pulsatile bleeding may indicate epidural bleeding secondary to a medial wall perforation.

5. Tapping, Repalpation, and Screw Placement.

The pedicle tract was undertapped with a 0.5 mm less diameter tap than the intended screw Following this, the pedicle tract was palpated again to make sure that the five osseous borders were intact. This second palpation often allowed palpation of distinct bony ridges confirming intraosseous position, and the tract length was remeasured with a hemostat. This measurement was compared directly adjacent to the screw to be placed to ensure appropriate screw length. The screw was placed slowly down the pedicle into the body in the same alignment to confirm that it was threaded properly, and allowed for viscoelastic expansion.

Post-operative care:

All patients were neurologically tested before leaving the operating room after recovery. All patients were given 3rd generation Cephalosporin (Cefotaxime 1 g every 12 hours) for one week and non-steroidal anti-inflammatory drugs was given according to patient tolerance. All patients wore lumbar brace, for 2-3 weeks, then the brace was discarded and the patients were advised to ambulate immediate postop but bending or twisting of the waist and raising more than 5 Ib was generally not allowed for 3 months. Limitations, such as preventing over exercise from climbing stairs, pushing or pulling movements, extended setting and extended standing, all of these behaviors were usually limited to 3-6 months. Post-op plain X-ray and CT were done to assess mid sagittal diameter of neural canal and screws position.

All patients were instructed to wear their brace during movement and take it off before going to sleep. Patients with only spine fracture were released from hospital on the second day following surgery. The patient's first return to the

outpatient clinic was 7 days following discharge, and the follow-up during that time focused on wound assessment, patient reassurance and a shift in the type of analgesics according to the patient's complaint.

Postoperative evaluation: The patients were reviewed at 2 weeks postoperatively for removal of stitches, clinical and neurological examination. Follow up was done after 6 weeks and 3 months. The following items were evaluated at each visit: Clinical evaluation included neurological examination, back pain, movement of the spine, return to work, satisfaction and complications. Plain X-rays and CT were done if needed.

Statistical analysis:

The data recorded was analyzed using the statistical Package, version 20.0 (SPSS Inc., Chicago, Illinois, USA). Quantitative data were presented as mean ± standard deviation (SD) and average. Qualitative data was expressed as a frequency and percentage of data.

The following tests were done: Chi-square (X2) test of significance was used in order to compare proportions between qualitative parameters. independant t-test of significance or Mann-Whitney U test were used when comparing between the mean samples. P-value < 0.05 was considered significant.

RESULTS

Among 50 patients in the study, male patients were 42% (26% operated by image assisted technique, 16% operated by free hand techniques), and female patients were 58% (38% operated by image assisted techniques, 20% operated by free hand techniques) **(Table 1)**.

Table(1): Distribution of free hand vs image assisted fixation cases according to regarding gender

Sex	N		Percent	
Male	Image assisted	13	26%	42%
	Free hand	8	16%	
Female	Image assisted	19	38%	58%
	Free hand	10	20%	
Total	Image assisted	32	64%	100%
	Free hand	18	36%	

Patients in free hand technique with fractures were 50%, patients with lythesis were 38.8%, and patients with scoliosis were 11.2%, while in image assisted technique patients with fractures 40.9, in lythesis was 50% and 9.4% in scoliosis **(Table 2)**.

Table (2): Distribution of cases according to type of pathology (n=50)

Technique	Free hand		Image assisted	
Pathology	**No of patients**	**Percentage**	**No of patients**	**Percentage**
Fractures	**9**	**50%**	**13**	**40.6%**
Lythesis	**7**	**38.9%**	**16**	**50%**
Scoliosis	**2**	**11.2%**	**3**	**9.4%**
Total	**18**	**100%**	**32**	**100%**

Among 50 patients in the study there were 32 cases operated by image assisted technique, while 18 cases operated by free hand technique **(Table 3)**.

Table (3): Surgical techniques used in study

Surgical Technique	Frequency	Percent
Image assisted	**32**	**64.0**
Free Hand	**18**	**36.0**

The distributions of screws in free hand technique, 24% of patients had good screws positions, 4% medial positions, 8% Lateral screw positions, in image assisted technique 56% had good screw positions, 6% lateral positions, and 2% had medial screws positions **(Table 4)**.

Table(4): Different screw positions

Screw positions		No of patients	Percent	P value
Free hand technique	**Good**	**12**	**24%**	**<0.01**
	Medial	**2**	**4%**	
	Lateral	**4**	**8%**	
	Total	**18**	**36%**	
Image assisted technique	**Good**	**28**	**56%**	**<0.01**
	Medial	**1**	**2%**	
	Lateral	**3**	**6%**	
	Total	**32**	**46%**	

As regard accuracy of screws positions in free hand technique, 3.7% of screws were medially, 7.4% was laterally, while the percentage of good screws was 88.9%. In image assisted technique, 0.75% was in medial position, 5.3% in lateral positions, while 94% good positions **(Table 5)**.

Table(5): The percentage of screws in different techniques

Technique / Screws positions	Free hand technique	Percentage	Image assisted technique	Percentage	P value
Medial screws	4	3.7%	2	0.75%	<0.01
Lateral screws	8	7.4%	14	5.3%	<0.01
Both medial and Lateral	12	11%	16	6.0%	<0.01
Good screws	96	88.9 %	248	94%	<0.01
Total screws	108	100%	264	100%	<0.01

The complicated cases were one case (5.5%) in free hand technique of total 18 cases, and also only one case (3.1%) in image assisted technique cases of total 32 cases **(Table 6)**.

Table (6): Complications in both techniques

Technique	No of Cases	No of complicated cases	Type of complications	Percentage	P value
Free hand	**18**	**1**	**Nerve root irritation**	**5.5%**	**0.001**
Image assisted	**32**	**1**	**CSF leak**	**3.1%**	**0.001**

Post-operative evaluations of patients according to pain (according to ODI) in cases operated by free hand technique post-operative was (19.4), while in cases operated by image assisted technique was 10 **(Table 7)**.

Table (7): Post op ODI in 2 Different techniques.

	Technique	N	MEAN	SD	MIN	MAX	P value
Post operation ODI percentage	**Image assisted**	**32**	**14.0**	**4.4**	**5.0**	**20.0**	**<0.001**
	Free Hand	**18**	**19.4**	**13.2**	**5.0**	**40.0**	
	Total	**50**	**13.4**	**9.7**	**5.0**	**40.0**	

There were improvements in pain (according to VAS) in cases operated by image assisted techniques in comparison to those operated by free hand technique. The mean of VAS in free hand technique immediate post op was 3.1, while in image assisted technique 1.9 **(Table 8)**.

Table (8): VAS In relations to Different techniques

VAS	Technique	N	Mean	SD	Min	Max	P value
VAS pre management	**Image assisted**	**32**	**6.9**	**1.3**	**4.0**	**9.0**	**>0.05**
	Free Hand	**18**	**6.8**	**1.3**	**5.0**	**9.0**	
VAS Post management	**Image assisted**	**32**	**1.9**	**0.6**	**1.0**	**3.0**	**<0.01**
	Free Hand	**18**	**3.1**	**0.7**	**2.0**	**4.0**	
Vas after 3months	**Image assisted**	**32**	**1.3**	**0.4**	**1.0**	**2.0**	**<0.01**
	Free Hand	**18**	**2.0**	**0.8**	**1.0**	**3.0**	
VAS difference	**Image assisted**	**32**	**5.1**	**1.3**	**3.0**	**7.0**	**0.001**
	Free Hand	**18**	**3.7**	**1.4**	**1.0**	**6.0**	
Percent change of VAS pre and Post management	**Image assisted**	**32**	**311.5**	**161.6**	**100.0**	**700.0**	**<0.01**
	Free Hand	**18**	**129.6**	**64.9**	**25.0**	**250.0**	

Blood loss in free hand technique was 219.4 cc, while in image assisted technique was 330.9cc **(Table 9)**.

Table (9): Blood loss in different technique

	Technique	N	Mean	SD	MIN	MAX	P value
BLOOD LOSS	**Image assisted**	**32**	**330.9**	**77.8**	**200.0**	**550.0**	**<0.001**
	Free Hand	**18**	**219.4**	**31.1**	**190.0**	**310.0**	

Anteroposterior and lateral radiograph images showed flexion distraction injury after the indirect reduction and posterior instrumental fusion using freehand technique **(Figure 1)**.

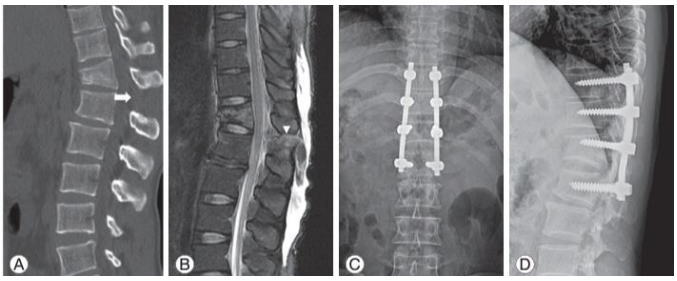

Figure (1): Pre and post-operative thoracic vertebra fixation by freehand technique

DISCUSSION

The free-hand pedicle screw technique has been well described and one inserts the pedicle screws based on the anatomical landmarks and the tactile feel of probing the pedicles. *Kim et al. (2010)* reported a low complication rate with this technique. It should be noticed that the accuracy of screw position remains primarily a function of surgical skill together with experience and is associated with a steep learning curve.

This study was a prospective and retrospective study of patients with an average age of 48 years.

Amiot et al. (2010) reported that the accuracy rate in freehand technique was 90.1% with revision rate (3%), while in image assisted technique was 95% with zero revision rates.

Gertzbein and Robbins, (2011) reported that the accuracy rate in freehand technique was 71.9, while was 89% in image assisted technique.

Merloz et al. (2013) reported that the accuracy rate in image assisted technique was 90 %, while the accuracy rate was 86 % in freehand technique.

Laine et al. (2014) reported that the accuracy rate in image assisted technique was 95.4% while was 88.8% in freehand technique.

In this study, the types of pathology were 22 thoracolumbar fractures, 5 deformity, and 23 spondylolistheses. In free hand technique, we had mal-placed screws in only 6 patients, four of them breached the lateral cortex of the pedicle and two breached the medial cortex of the pedicle with accuracy rate 89% and 2% revision rate (intra op) while in image assisted technique there were only in 4 patients 3 of them breached the lateral cortex of the pedicle, and one breached medially with accuracy rate 94% with zero revision rate.

Amiot et al. (2010) reported that the mal-placed screws in free hand technique

were in 11 patients, 6 of them breached the lateral cortex of the pedicle and 2 of them breached the medial cortex while 3 patients breached other perforations with accuracy rate 90.1% and revision rate 3% (intra op), while in image assisted technique there were 16 patients with mal-placed screws 8 of them breached the lateral cortex and 4 of them breached the medial cortex, while 4 breached other perforations with accuracy rate 95% and revision rate zero%.

In this study, in free hand technique, we had 12 mal placed screws,8 of them perforate the lateral cortex, while only 4 screws breach medially ,all of them were (grade A) breach but in image assissted technique 14 screws breach laterally ,2 only breach medially , all of them were (Grade A) breach.

Laine et al. (2014) reported that the mal-placed screws in free hand technique were in five patients, 3 of them breached the lateral cortex of the pedicle and 2 of them breached the medial cortex with accuracy rate 86.8% with revision rate 4% (intra op), while in image assisted technique there were only 3 patients with mal-placed screws 2 of them breached the lateral cortex and one of them breached the medial cortex with accuracy rate 95.4% with revision rate 0%.

In this study, in free hand technique, we had 12 mal placed screws, 8 of them perforate the lateral cortex, while only 4 screws breach medially, all of them were (grade A) breach but in image assisted technique 14 screws breach laterally, 2 only breach medially, all of them were (Grade A) breach.

Amiot et al. (2010) reported that the mal-placed screws in free hand technique were in 27 screws, 19 screw breach laterally, 8 screws breach medially, 25 were (Grade A) breach and 2 (Grade B) breach, while in image assisted technique 16 screws breach laterally, and 5 screws breach medially, all of them (Grade A) breach, with no neurological complications in both.

Gertzbein and Robbins, (2011) reported that the mal-placed screws in free hand technique were in 12 patients, 8 of them breached the lateral cortex of the pedicle and 2 of them breached the medial cortex and 2 breach other perforations with accuracy rate 71.9%, while in image assisted technique there were 7 patients with mal-placed screws 5 of them breached the lateral cortex and 2 of them breached the medial cortex with accuracy rate 89%.

Merloz et al. (2013) in free hand technique we had mal-placed screws in only 4 patients, 2 of them breached the lateral cortex of the pedicle and 2 breached the medial cortex of the pedicle with accuracy rate 86% while in image assisted technique there were 8 patients 5 of them breached the lateral cortex of the pedicle with accuracy rate 96%, while 3 breached the medial cortex.

Laine et al. (2014) reported that the mal-placed screws in free hand technique were in 37 screws, 21 screw breach laterally, 7 screws breach medially and 7 screws other perforations, 35 were (Grade A) breach and 2 (Grade B) breach, while in image assisted technique 9 screws breach laterally, and one screw breach medially, all of them (Grade A) breach with no neurological complications in both techniques.

CONCLUSION

Freehand technique of pedicle screw placement when performed in a step-wise manner was an accurate, reliable, safe, less time-consuming, with lesser radiation and cost-effective method of insertion to treat a variety of spinal disorders.

Imaging technique was safe and effective with high accuracy and has the benefit of increased visualization of a pedicle's trajectory, but can result in increased morbidity associated with radiation exposure, increased time expenditure, and possible workflow interruption

So freehand technique was as good as the image-assisted technique in comparison to safety and accuracy. Using both techniques together can result in high accuracy and efficacy that can reach up to 100%, and decreasing the time of radiations exposure and so decreasing the hazards that resulting from radiations, although decreasing the time of operations and blood loss, although make transpedicular thoracolumbar fixation surgery easy procedure without need to a steep learning curve and experienced surgeon.

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دراسة مقارنة تثبيت الفقرات الصدرية والقطنية عن طريق مسمار العنق بواسطة تقنية اليد الحرة مقابل تقنية إستخدام أجهزة التصوير

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خلفيـــة البحـــث: يعـــد تثبيـــت الفقـــرات الظهريـــة والقطنيـــة باســـتخدام المســـامير الحـــل الامثـــل فـــى تصـــحيح التزحـــزح الفقـــارى والامـــراض الرضـــية والتنكســـية واعوجـــاج العمـــود الفقـــرى وكســـور العمـــود الفقـــرى،ويتم حاليـــا اســـتخدام مجموعـــة متنوعـــة مـــن التقنيـــات للمســـاعدة فـــى وضـــع المســـامير اهمها جهاز الاشعة.

الهـــدف مـــن البحـــث: تقيـــيم دراســـة ســـلامة ودقـــة وضـــع المســـمار باســـتخدام تقنية يدوية (اليد الحرة) مقابل تقنية إستخدام اجهزة التصوير الحديثة.

المرضـــي وطـــرق البحـــث: أجريـــت الدراســـة علـــى 50 مريضـــا بمستشـــفيات جامعـــة الأزهـــر تـــم إدخـــالهم المستشـــفى لإجـــراء جراحـــات بـــالعمود الفقـــرى وتـــم تقســـيمهم إلـــى مجمـــوعتين: مجموعـــة تقنيـــة اليـــد الحرة(المجموعـــة الأولـــى) ومجموعـــة تقنيـــة جهـــاز التصـــوير(المجموعة الثانيـــة). وقـــد أجريـــت الدراسات فى الفترة ما بين مارس 2019 إلى نوفمبر2020.

نتـــائج البحـــث: أظهـــرت الدراســـات أن نتـــائج تثبيـــت الفقـــرات الصـــدرية والقطنيـــة بواســـطة تقنيـــة اليـــد الحـــرة كانـــت مـــن حيـــث الدقـــة تصـــل الـــى 89% حيـــث تـــم تثبيـــت 108 مســـمار اثناعشـــر مســـمارا فقـــط، بينمـــا باســـتخدام تقنيـــة

التصـــوير بواســـطة اجهـــزة التصـــوير وصـــلت إلـــى 94% حيـــث تـــم تثبيـــت مايقرب من 264 مسمارا.

الإســـتنتاج: تثبيـــت الفقـــرات الصـــدرية والقطنيـــة باســـتخدام تقنيـــة اليـــد الحـــرة يماثـــل تقنيـــة اســـتخدام اجهـــزة التصـــوير مـــن حيـــث الدقـــة والأمـــان اذا تـــم عـــن طريـــق يـــد خبيـــرة, كمـــا أنـــه يـــوفر الجهـــد والوقـــت ويقلـــل مـــن التعـــرض لأشـــعة الأجهـــزة, إذا تـــم إســـتخدام كلتـــا التقنيتـــين فـــى جراحـــات العمـــود الفقـــرى فـــإن ذلـــك يمكـــن مـــن الإســـتفادة مـــن مميزاتهمـــا معـــا فـــى بلـــوغ نســـبة دقـــة قـــد تصـــل إلى 100% ويساعد فى تقليل مخاطر كلتا التقنيتين.

الكلمـــات الدالـــة: تثبيـــت الفقـــرات القطنيـــة، الفقـــرات الصـــدرية، تقنيـــة اليـــد الحرة، تقنية التثبيت بواسطة أجهزة التصوير.