29 TOTAL DISC REPLACEMENT

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Knowledge gathered from experiments and experience grows like a tree, and we later begin to collect the tree's fruit. Regarding the spine, we have started to obtain the products of rigid and dynamic stabilization from the synthesis of anatomy, physiology, biology, and mechanics. One of these products is the "disc prosthesis".

1. Background

When we look at the development of disc replacement, we will see that it is not very dated. As the first person to perform a discectomy, Barr [1] declared in a later article, "Once a disc has been removed, we can no longer claim the spine to be anatomically or mechanically normal." Barr, in keeping with my opinion, subsequently stated the problem further: "The disc can be removed, but this operation is not sufficient, and I do not know what else can be performed."

French van Steenbrugghe [2] were the first to receive a patent for placing a dynamic structure in the vacated disc space. A dynamic prosthetic was first used in patient treatment by the Swedish spinal surgeon Fernström [3] in 1966. The prosthetic used by Fernström was a steel ball. He classified the ailments into two groups: "lumbar disc herniation" and "degenerative disc disease". His most notable finding was that the treatments of the patients in the disc herniation group were more successful, but the patients in the degenerative disc group only ceased to have lower back pain. However, Fernström's method has not become prevalent. Because the steel ball is solid and spherical, increased load on the point where the cartilage meets the vertebral end plates causes the cartilage to break and lodge into the vertebral body, and the prosthetic thus loses its dynamic property after a period of time.

In subsequent years, studies were performed mostly on the replacement of nuclear material. In 1973, Urbaniak et al. [4] injected silicon Dacron implants into chimpanzees and observed aberrant bone formation along with bone resorption. In 1974, Schneider and Oyen [5] injected liquid silicon into the disc space following discectomy and ensured that the silicon froze in the disc space. Froning [6] received a patent for an inter-disc device that remained in the vacated disc space that could collapse or expand and had a pocket, but he never applied this technique to patients.

Fassio [7] made an elastic prosthetic that had a synthetic resin on the inside with a frame outside and, along with Ginestie [8], applied itfirst to monkeys and later to three patients.However, their results were not as good as expected; as disc height decreased, the material was displaced because it became squeezed, and movement was not observed.

In 1984, Germans Karin Büttner-Janz and Kurt Schelnack accomplished the process of total removal of a disc and replacement with an artificial disc. After intensive biomechanical material studies, they created a disc prosthetic made up of three parts. The first disc prosthetic was made of rigid metal plates as the top and bottom pieces with a plastic nuclear material connected to these metal plates. The cartilage attached to the vertebrae by lodging to the

serrated bumps on the metal plates and to the vertebral end plates. Based on results in patients and the problems encountered after their application, the disc prosthetics were modified twice and took their final form as Charité III. The artificial disc came to be called Charité III because it was used at the Charité hospital connected to Humboldt University. In 1987, when Karin Büttner-Janz and Kurt Schelnack [9] published their first results, they emphasized that disc prosthetic surgery with a ventral approach was now an alternative treatment method. A year later, when these researchers published findings from a second set of patients, they were extremely pleased with their results. Compared to before surgery, 98% of patients improved after surgery [10]. After this date, the use of the Charité III disc prosthetic spread throughout the world. Later, Marnay [11] devised the "ProDisc", which is known as the "ball-socket" and has a slippery polythene substance between the plates. Marnay has published positive results from 11 years of clinical observations. Over the years, many disc prosthetics have been made and used clinically. To treat degenerative disc disease today, prosthetic discs are often the best approach.

2. Indications

It should not be overlooked that of the lumbar disc prosthetic candidates, a majority of the patients have degenerative disc disease without neurological problems. The ultimate goal of the treatment is to increase the quality of life of the patient. For this reason, the primary goal should be to give the patient the treatment that will provide the best chance for recovery or improvement, such as by performing back exercises to the extent that the patient can perform them under the doctor's guidance and achieving medical health without surgery. Only those patients who cannot sustain the medical treatment and exercise program should be candidates for surgery. Along these lines, Huang [50] has reported that only 5% of lumbar surgery patients have indications for total disc replacement (TDR).

Those patients with single-level degenerative disc disease form the best candidate group for lumbar disc prosthesis surgery. A lumbar disc prosthesis can be made for two disc spaces by pushing indications; however, this approach is not practiced in our clinic, and we do not recommend such an approach. For disc surgery, the patient needs to be complaining of pain, and instability of the disc needs to be detected radiologically (Figure 1). Although magnetic resonance imaging (MRI) is a good method to detect disc status, MRI can give falsepositive results [12,13]. Even though many articles have recommended against it, to obtain as much information as possible from the patient, we use discography in our clinic [14-17]. In discography, the presence of annulus tearing and pain provocation is observed (Figure 2). To better image the tears in the annulus, a disco-BT is recommended but not made mandatory. I believe there is benefit in emphasizing one point that does not receive much attention in the literature. Due to the increased pressure caused by the injections into the disc, the sides of a tear become mechanically irritated. Additionally, the dye used can chemically irritate sensitive nerve endings. Both of these cause pain. If a tear is notably large or if there are many tears, pain provocation is not observed, due to the inability of the liquid to cause pressure in the disc, which yields falsenegative results.

In this case, we cannot say that the disc that the procedure is performed on is not the source of pain. If the patient is showing more than the expected reaction to the injection, it could be a sign that the patient is psychologically unstable. In such patients, it is necessary to be careful in making the decision to perform surgery. The point to focus on with these procedures is the importance of the injection of intradiscal local anesthetic after the initial injection. Normally, the local anesthetic reduces the pain by blocking sensitive nerve endings. This situation also shows that this disc is the source of pain. For us, the ideal patient group is composed of adults ages 20-40, showing a problematic disc on MRI, with disc heights no less than 5 mm, with no facet joint problems, and with good bone quality.

3. Contraindications

3.a. Osteoporosis

Because bone quality is compromised in patients with osteoporosis, the spine can fracture during the placement of the rigid metal disc. Even though most artificial discs are made of metals or nonmetals, they are more rigid compared to normal discs. Therefore, they have little to no shock-absorbing qualities and transfer the load to a bottom segment.

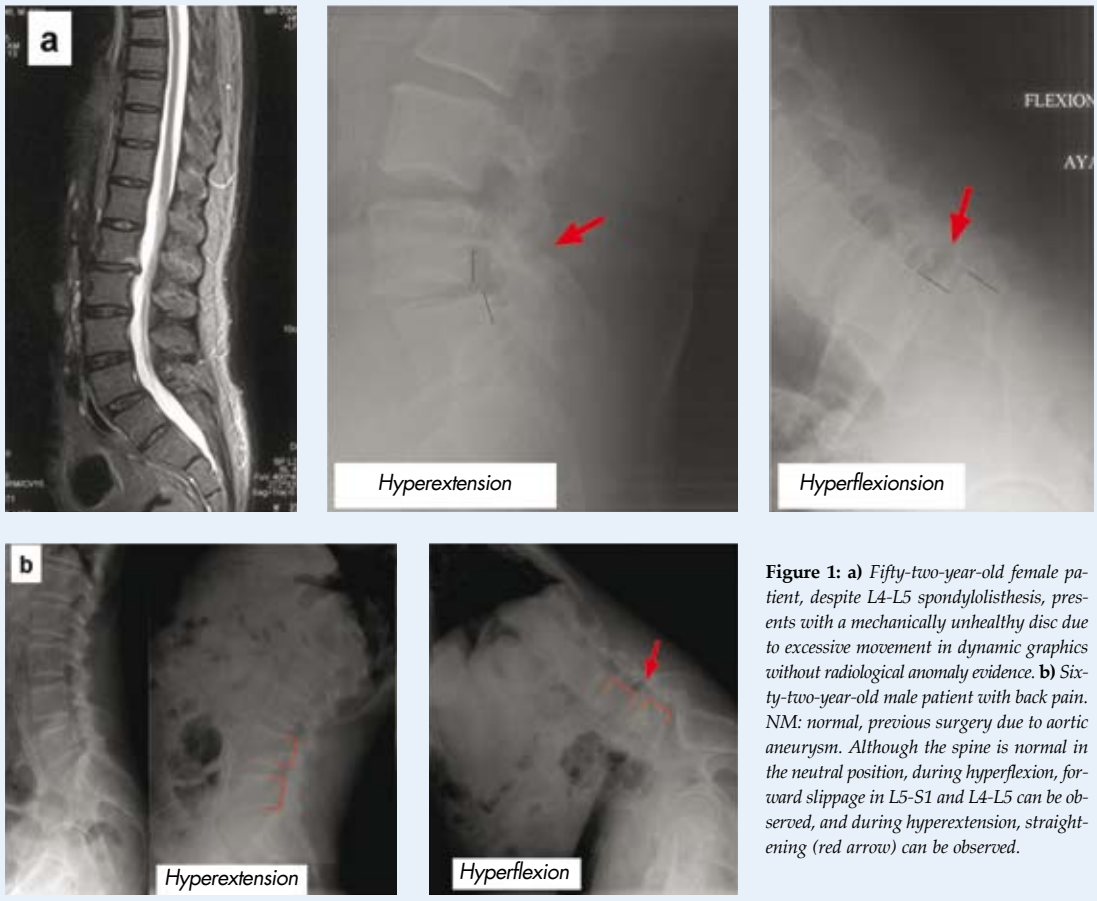

Figure 1: a) *Fifty-two-year-old female patient, despite L4-L5 spondylolisthesis, presents with a mechanically unhealthy disc due to excessive movement in dynamic graphics without radiological anomaly evidence.* **b)** *Sixty-two-year-old male patient with back pain. NM: normal, previous surgery due to aortic aneurysm. Although the spine is normal in the neutral position, during hyperflexion, forward slippage in L5-S1 and L4-L5 can be observed, and during hyperextension, straightening (red arrow) can be observed.*

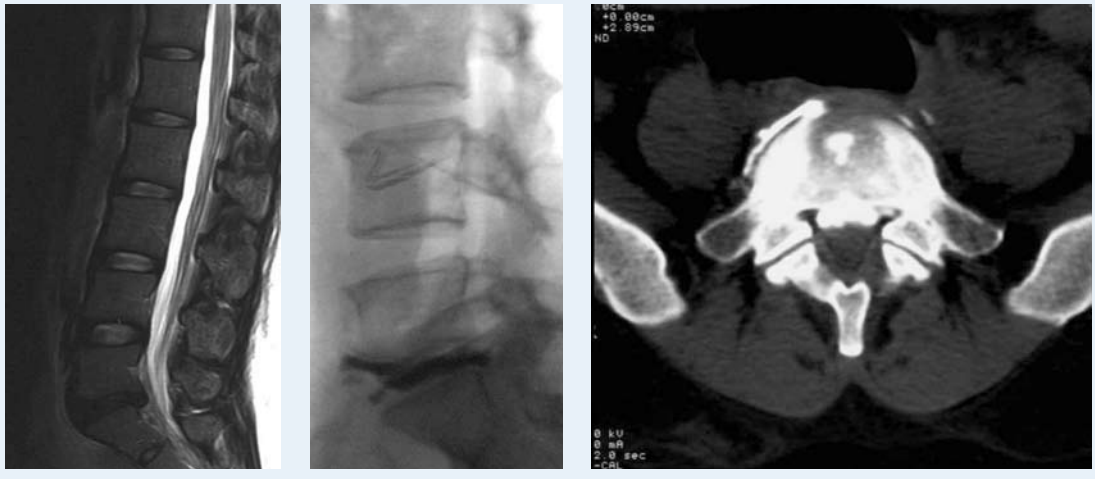

Figure 2: *Discography gives information regarding the disc's internal structure and the annulus, while the presence of pain provocation is determined.*

The spine can easily break in patients when the load is slightly above normal, especially in patients with two-disc prosthetics where the spine in between can break easily. For this reason, patients with calcium metabolism disorders or patients using cortisone are not suitable for disc prosthetic surgery.

3.b. Problems with the Anterior Approach

It is fairly hard to reveal the anterior part of the disc to place a prosthetic in patients who have had prior abdominal surgery. These patients are not suitable for disc prosthetic surgery. Additionally, artery bifurcation observed by MRI or Blalock-Taussig angiography is important (Figure 3). If bifurcation ends right above the disc space, re-revealing the anterior part of the disc enough to place a prosthetic is difficult, and these patients are also not suitable for disc prosthetic surgery [18].

3.c. General Health

In patients who will undergo surgery, as with any instrumentation surgery, there should be no infections in the teeth, skin, or other similar sites. Those with immune system deficiencies, those taking medication to treat such deficiencies, and those with rheumatoid problems are clearly outside of the suitable group for this surgery.

3.d. Obesity

Important surgical problems could present in obese patients. The slightest blood pressure decrease during surgery could cause renal nutrition deficiency and ischemic renal failure. Due to severely fatty livers in this group, liver functions quickly fail, and hepatorenal syndrome could develop. This pathology has a notably high mortality [19].

In particular, the presence of an anatomic sacral slope and an excessive load on the bottom disc due to obesity will cause the prosthetic to slide. Another important problem is the difficulty of producing a surgery space for obese patients.

3.e. Nerve Root Compression

Unless the compression on the nerve root is removed, it is not possible to treat nerve root compression by placing a prosthetic. Lumbar disc herniation is not an absolute contraindication. Through the anterior lumbar, especially with microsurgery, it is possible to remove the piece compressing the disc and to place a prosthetic [20].

3.f. Additional Spinal Problems

Prosthetic surgery is contraindicated in patients with facet joint pathology. Facet joint disease is also a cause of pain in itself. In spinal stenosis, it is not guaranteed that the channel will relax by removal of the disc and subsequent placement of a prosthesis. For this reason, it is beneficial not to perform such a surgery. If spondylolisthesis is ischemic, then surgery is clearly contraindicated. If degenerative spondylolisthesis displacement is more than 3 mm, then it is questionable whether the facet joints are healthy. Patients with facet joint pathology do not constitute a suitable group of patients for disc prosthesis.

Figure 3: *Arterial bifurcation measurement via MRI and BT angiography.*

3.g. Disc Height

Facet joint problems are possible for discs with a height of less than 5 mm. A shortened annulus and possible localized calcifications indicate—even if a prosthesis was placed—that the disc space will be rigid. Patients in this group are not candidates for disc prosthesis.

3.h. Scoliosis

If we accept spinal bending up to nine degrees as normal variation,

larger deformations will cause an asymmetrical load on the prosthesis and will cause the prosthesis to dislocate.

3.i. Prior Spinal Surgery

Patients who have had prior laminectomy or discectomy are not suitable for TDR. However, those patients with preserved flaval ligaments and those with unaffected facet joints after surgery could later become candidates for an anterior disc prosthesis if necessary [21].

3.j. Psychological Evaluation

One of the most important evaluation criteria is a psychological evaluation. Lack of a psychological evaluation can cause problems for the surgeon. Patients who are, knowingly or unknowingly, pursuing secondary gain and those with characteristic flaws, heavy depression, or psychosis are contraindicatory for this and any other type of surgery, except emergency cases.

4. Biomechanics and Disc Prostheses

In humans, the spinal discs are under heavy mechanical stress. Discs are more resilient to stress than bones, and discs deform only after bones are broken. Experimental studies have shown that a healthy disc can handle loads up to 17,000 N [22,23]. Discs convert their compressive load into a tensile load on their annulus via the hydrostatic pressure formed by their internal interstitial fluid. While interior annulus fibers absorb the shock, stiffer outer fibers dissipate the compressive load [24]. The high tensile strength of the annulus prevents the degenerative disc from bulging. As the nucleus dehydrates, swelling pressure decreases. When the strength of the annulus decreases, the effect of the load decreases in the load dissipation discussed above. The disc subsequently transfers its entire load to the bone structure [24]. Pathological loads on the disc play an important role on disc degeneration. In animals, static loads cause more degeneration compared to cyclic loads [25]. When a load is excessive, disc metabolism is reduced proportionally to the intensity of the load, and catabolic enzyme production within the disc increases. In earlier stages of degeneration, temporary increases of dynamic disc cell number increase load and, along with compromised metabolism, cause a decrease in disc capacity. [26]. In general, when we look at the total spine and not only one disc, the overall balance of the frontal and sagittal planes of a vertebra is important. In the frontal plane, the spine is straight. In the sagittal plane, the relationship between a normal lumbar lordosis and a normal pelvis has an important effect on the overall balance. This relationship can be expressed through measurements performed on the sagittal plane. These measurements are, first, the sacral slope; second, the pelvic tilt; and last, the pelvic incidence, which is a sum of the first two measurements [27] (Figure 4). What makes these measurements important is the necessity of considering the balance prior to placing a prosthetic to avoid abnormal loads on it, thereby avoiding the displacement of the prosthetic. As the disc degenerates, the load transition also deteriorates. Normally, during spinal load, while the majority of the load travels down the anterior column,

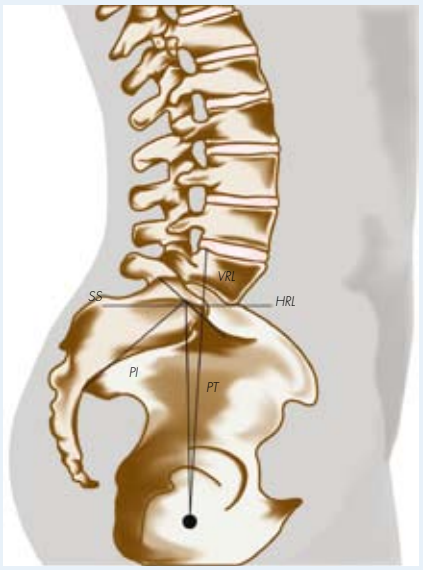

Figure 4: *Pelvic incidence (PI): Gives information about pelvic morphology. PI is a constant that depends on the person. PI is the angle between the straight line through the middle of the sacral end plate and the line connecting the center of the femur head and the dorsal sacral plate. Sacral slope (SS): the angle between the line through the S1 end plate and the horizontal reference line (HRL) going through thepromontorium. Pelvic tilt (PT): the angle between the line connecting the middle of sacral far plate to the femur head and the line from the femur head to the vertical reference line (VRL).*

only 18% of it utilizes posterior columns [22]. The transduction of the load down the posterior elements also depends on the sagittal balance of the spine, the degree of disc degeneration, and the posture the vertebra takes during daily life. As the disc degenerates, the load moves from the annulus. Subsequently, as the intradiscal structure hardens, the impaired disc spreads the load everywhere, causing the posterior columns to carry more load than usual. This situation demonstrates how degeneration affects neighboring structures adversely. During the start of degeneration, it is hard to locate the instantaneous axis of rotation (IAR), which is normally located within the disc. However, once degeneration increases to the point of reduced elasticity of the disc and stabilizes, IAR moves to the cartilage end plate of the bottom vertebra. In this state, the disc will behave no differently from a normal disc with respect to its elasticity [28]. However, the disc height decreases, and spine biomechanics change. It is thought that in this last stage, the cause of pain is no longer the degenerative disc, but rather secondary effects on the muscles, ligaments, and articular facets caused by compromised spine balance.

Effect of Disc Prosthesis on Compromised Spine Biomechanics

A disc prosthesis converts the disc height to normal levels, allowing the foramen to open. By allowing the posterior annulus (dense in mechanical receptors) to stretch, the prosthesis corrects the proprioceptive capacity, which, in turn, is an important step in achieving spine balance. The goal is not increasing or decreasing final disc height but achieving normal disc height. The most problematic disc space is the lumbar 5–sacral 1(L5-S1) vertebral space. Due to the sacral slope, this disc's frontal height is high compared to its backside; thus, the choice of a prosthetic comparable to this disc's angle is important. By ensuring the load travels centrally and converting the degenerative disc's dynamic to normal from its increased or reduced elasticity, neighboring tissues are protected from abnormal loads. Although the IAR is usually at the manufacturing company's suggested site when a disc prosthesis is placed, the prosthesis should ideally be placed with its rotation center on the sagittal plane, slightly behind the spine's medial line and slightly below the cartilage end plate of the bottom vertebra [29]. Total disc prostheses allow for forward, backward, and sideways bending and rotation. Ligaments, the proprioceptive nervous system, and muscles control all these movements. While excessive movements are stopped by the original disc's anatomic structure, the disc prosthesis device itself limits them. The return of load and movement to normal in the segment containing a disc prosthesis will restore posture and improve spine balance [30].

5. Clinical Results

Among lumbar disc prostheses, the Charité is the most widely used. After Bütner-Janz and Schelnack [10] published their positive clinical observations, this prosthesis's use has become prevalent across the world. The first part of an important two-part study in the USA under the supervision of the Food and Drug Administration (FDA) was the comparison of multi-center, randomized, and fusion studies. This study found TDR to be more effective than fusion [31]. In the second part of the study, the disc prosthesis improved the range of motion (ROM) compared to before surgery. Because the disc height returned back to normal, cages between vertebrae had less subsidence [32]. Since that study, there have been many positive clinical results published regarding the Charité disc [31,33-35]. In contrast to all these positive results, the study published by Putzier [36] in 2006 was disappointing. Because the previously manufactured Charité was the oldest study and promised many years of success, Putzier used 84 Charité I, II, and III discs on 71 patients. This researcher's results indicated 60% of patients developed ankylosis. Although Putzier did not observe neighboring segment disease in 17% of patients who were defined as functional, these patients were less satisfied than those with fusion results. Putzier concluded by recommending the fusion technique. Although Putzier's thoughts pleased the defenders of fusion, it is hard to know how extensive the long-term follow up will be due to the need to consider the reality of human aging. A disc that was normal 17 years ago could go into ankylosis as a result of a natural process.

Why do we blame a prosthesis that has served its purpose for a period of time and subsequently gone into ankylosis when we should be applauding it? Additionally, 17% of the group had pain, but is the cause of pain the level of the prosthesis or a

spine that has aged 17 years? If these results had been observedthree to five years earlier, they might have been more meaningful, but 17 years is quite a long time! Freeman and Davenport [37], through literature searches involving a randomized double-blind study, two systematic studies, seven prospective studies, and eight retrospective studies, investigated the clinical outcomes of Charité and ProDisc II. These authors concluded through evaluations of outcomes of TDR and lumbar fusion surgery that neither prosthesishas an advantage over the other. They also stated that long-term effects on neighboring segments and the complications that might arise later are not yet clear.

Punt et al. [38] determined that 75 patients in the Netherlands who received the SB Charité disc had continued, unexplained back and leg pain. These researchers stated that the sources of late complications observed in 1000 patients who received a Charité disc prosthesis are chips, neighboring segment degenerations, facet joint degenerations, and prosthesis migration. Researchers who applied fusion to 37 of these patients emphasized the dangerous complications that could arise later from disc prosthesis surgery. The ProDisc, known as the "ball-socket" in the literature due to its structure, later came into use. In this mechanism, a hemisphere moves in its socket and includes a slippery polyethylene substance, which is also used in hip joint prostheses, between the plates that helps with movement and can prevent wear debris over time. Marnay [11] was the first to design and publish results of this disc in patients. ProDisc research groups have been formed with Marnay, and positive clinical results have been published [39,40]. A study under FDA supervision about ProDisc was published in 2007. While emphasizing the benefits of ProDisc in many parameters compared to fusion, the study was completed with 0% complications [41].

The Maverick disc also works with a "ball-socket" mechanism. What makes it different from ProDisc is that it is made of two parts (male and female) and lacks a polyethylene piece in the middle to prevent wear debris. The center of motion, especially when placed in the disc space, is designed to fall behind the spinal medial line, and the disc is a metal-on-metal structure. The Maverick received approval for use in Europe in 2001. In 2003, after FDA approval in the United States, the Maverick has come under close surveillance for material, strength, wear debris, and ease of surgical implementation. Successful results from a series of clinical studies performed in France were published by Le Huec [42]. In a separate study, these researchers applied the Maverick disc prosthesis to patients presenting with healthy facet joints who had first- and second-degree degenerated discs with fatty degenerated and thus weak muscles. While emphasizing the success of the study, these researchers reported the reduction of the load on facet joints, even with the presence of weakened muscle support [43].

Currently, clinical studies are being performed on MobiDisc, AcroSex, and Active-L, all of which had successful preliminary results. In our clinic, the Maverick disc has been used in a 20-patient series. To achieve objective results for pre- and post-surgery, the patients have been observed by the Physical Therapy and Rehabilitation Department of the American Hospital. The visual analogue scale and Oswestry point system, performed pre- and post-surgery, have shown better results than single-level fusion in every aspect. In our meticulously chosen patient group, a complication rate of 0% has been observed [20,44]. Together with the Physical Therapy and Rehabilitation Department, a treatment regimen has been developed for after surgery. To those patients presenting to our clinic with disc herniations and nerve root ending compressions within channels, disc prostheses are placed via anterior discectomy. It should be noted that lumbar disc herniation is not contraindicatory [45].

Given these successes, why have we placed so few disc prostheses? The reason is that for those patients previously indicating lumbar disc prostheses, we currently place posterior dynamic supports. By repairing these patients' discs and providing dynamic stabilization, we have observed that their discs almost return to normal within one year of follow-up. No prosthesis is as good as a patient's own disc. In the United States and in Europe, many centers place prostheses in patients' discs if their posterior walls are torn, but the discs contain liquid material, and the disc heights are almost intact. Many of these discs can be preserved by strengthening via a dynamic system without the need to replace the discs. We should also remember that many of the prostheses used currently do not resemble the original and, at minimum, do not have the effect of

spreading the load or absorbing shock. These prostheses provide movement within normal physiological limits and provide a healthy transfer of load downwards. It is not yet known what their effect on neighboring segments is [46].

6. Surgical Technique

The anterior approach to the lumbar region is discussed in another chapter of this book. The lumbar region is approached by following the minimally invasive method defined by Mayer [39]. A modification is added to this approach to see the work field better, and the peritoneal leaves are sewn onto each other to prevent the intestines and the omentum from blocking the field of vision [18]. The workspace is established by exposing the anterior part of the lumbar region and placing the right retractors. The size of the disc is determined with disc size measurement tools, and the median line is subsequently marked (Figure 5). Discectomy follows scope confirmation. Discectomy performed under a microscope reduces possible complications. At this stage, with measurement tools in the prosthesis set, disc height and angle are measured, and a suitable prosthesis is selected (Figure 6). The posterior annulus is removed if necessary. If osteophytes are present, they should be cleared. At this point, it is possible to remove any previously detected disc material that causes herniation within the channel. Afterwards, the prosthesis site is prepared with the use of the device provided to prepare the disc space under the microscope (Figure 7). The next step is to place the prosthesis under the microscope (Figure 8).

7. Complications

Internal organ damage, especially intestinal, can be observed. Vascular damage, especially venous damage, is important and could become fatal. It is quite possible to see vascular damage as more vessels are being slid off the top of the disc space. Arterial damage is less likely and is also easier to control and fix. During discectomy, disc roots could be damaged, the dura could open, and a cerebrospinal fluid (CSF) fistula could develop. The vertebra could break while placing the prosthesis [47] (Figure 9). The disc prosthesis could become embedded within the vertebra [48] (Figure 10), or the top part could slide off forward off the bottom part [49] (Figure 11). The prosthesis could also enter the disc space and compress the neural tissue.

The most serious complications are infection and an unsuccessful operation. Since 1989, over 1000 patients have had the SB Charité disc prosthesis applied. These patients are not part of a partnered or planned study. Of these cases, 75 who have complained of back and leg pain were followed up for two years. While 34% of this group required a second surgery, 6% of the causes of discomfort were determined to be major complications.

The majority of complications in this patient group were caused by embedding of the prosthesis in to the vertebra, neighboring segment disease, facet joint disease, incompatibility of disc space size,

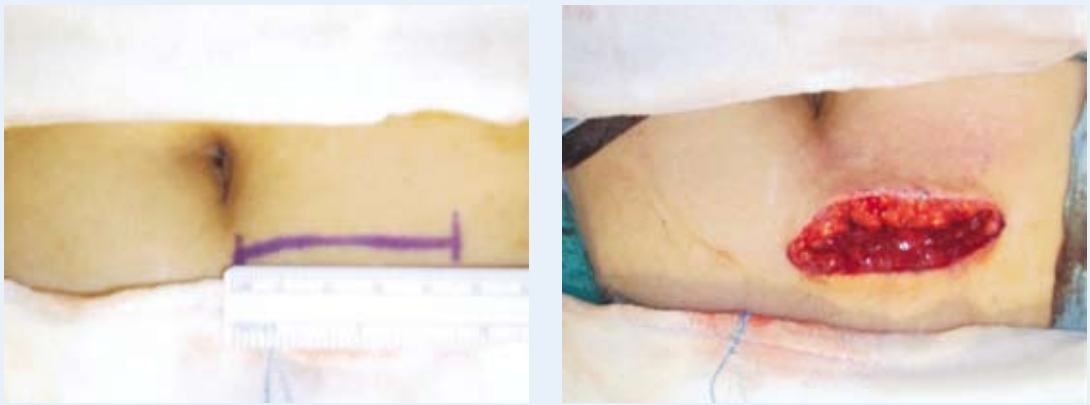

Figure 5: *Skin incision in the paramedian retroperitoneal approach.*

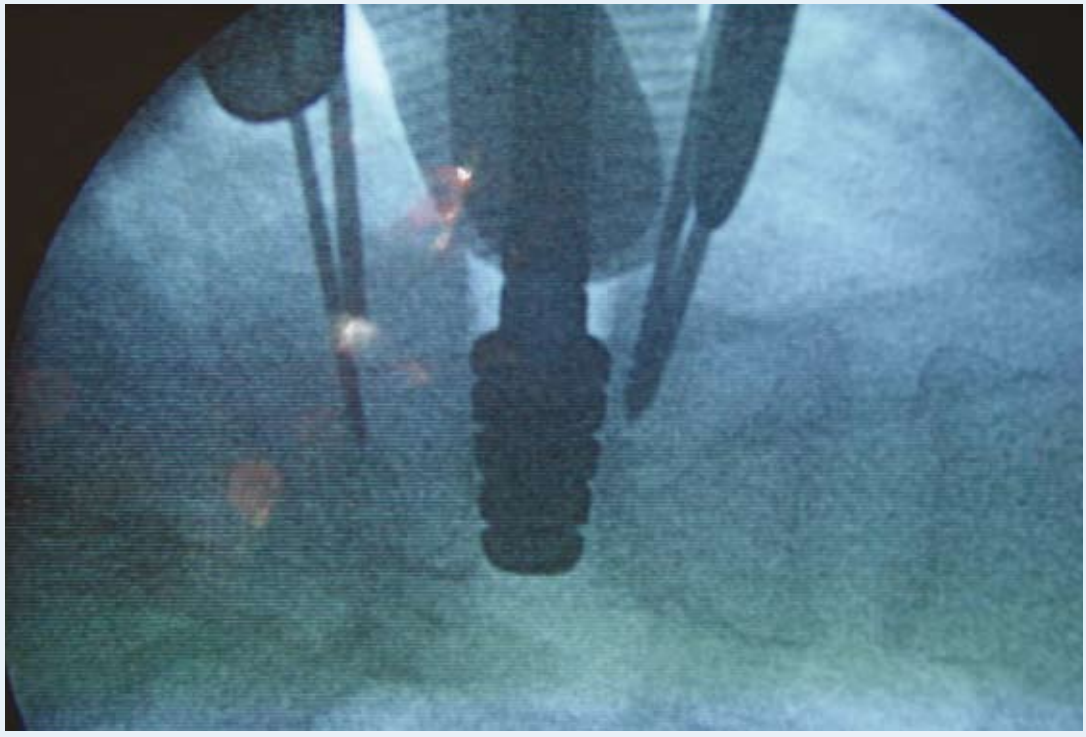

Figure 6: *Selection of a suitable disc prosthesis during a total disc replacement.*

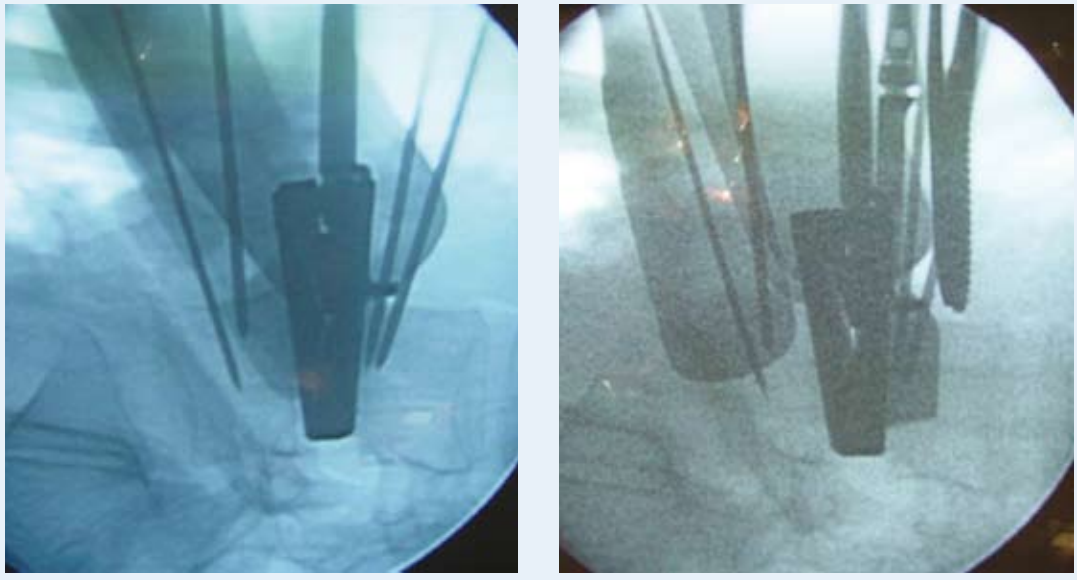

Figure 7: *Preparation of the disc prosthesis space within the disc space.*

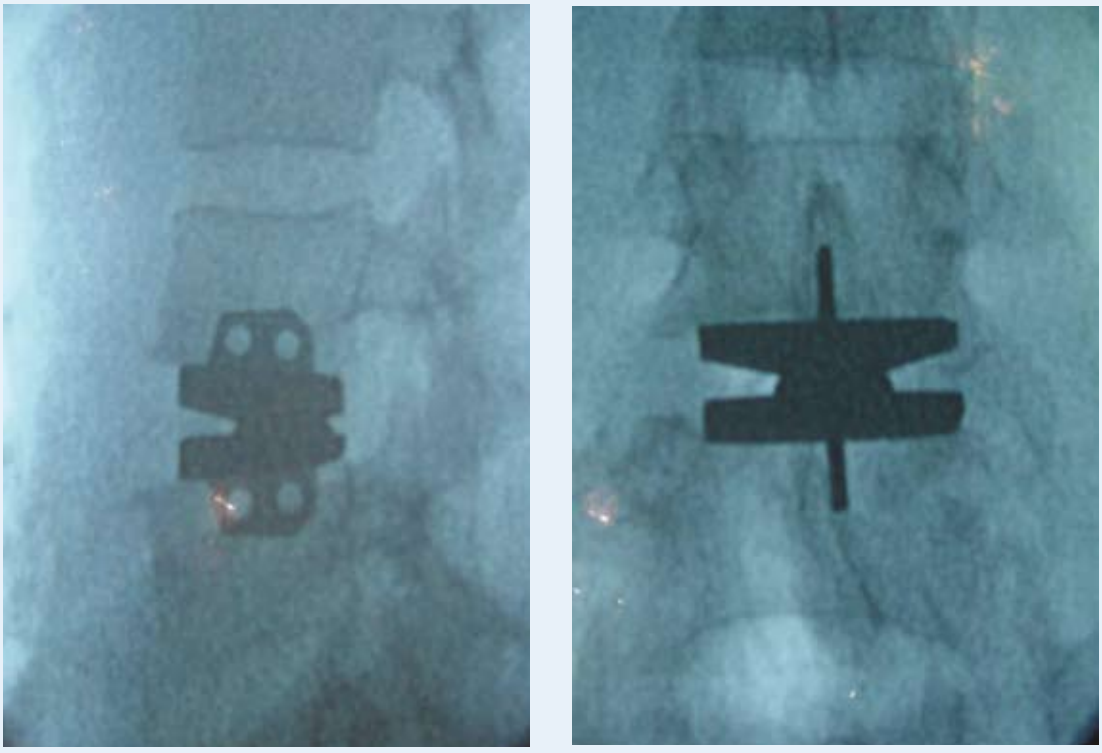

Figure 8: *After the placement of the disc prosthesis, it is checked under the microscope.*

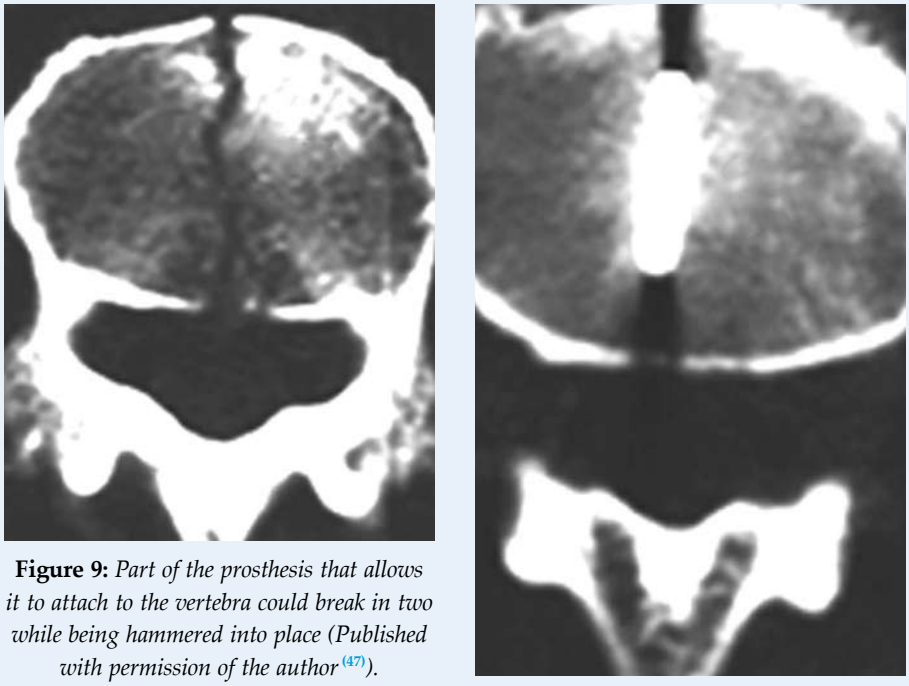

Figure 9: *Part of the prosthesis that allows it to attach to the vertebra could break in two while being hammered into place (Published with permission of the author*[47]*).*

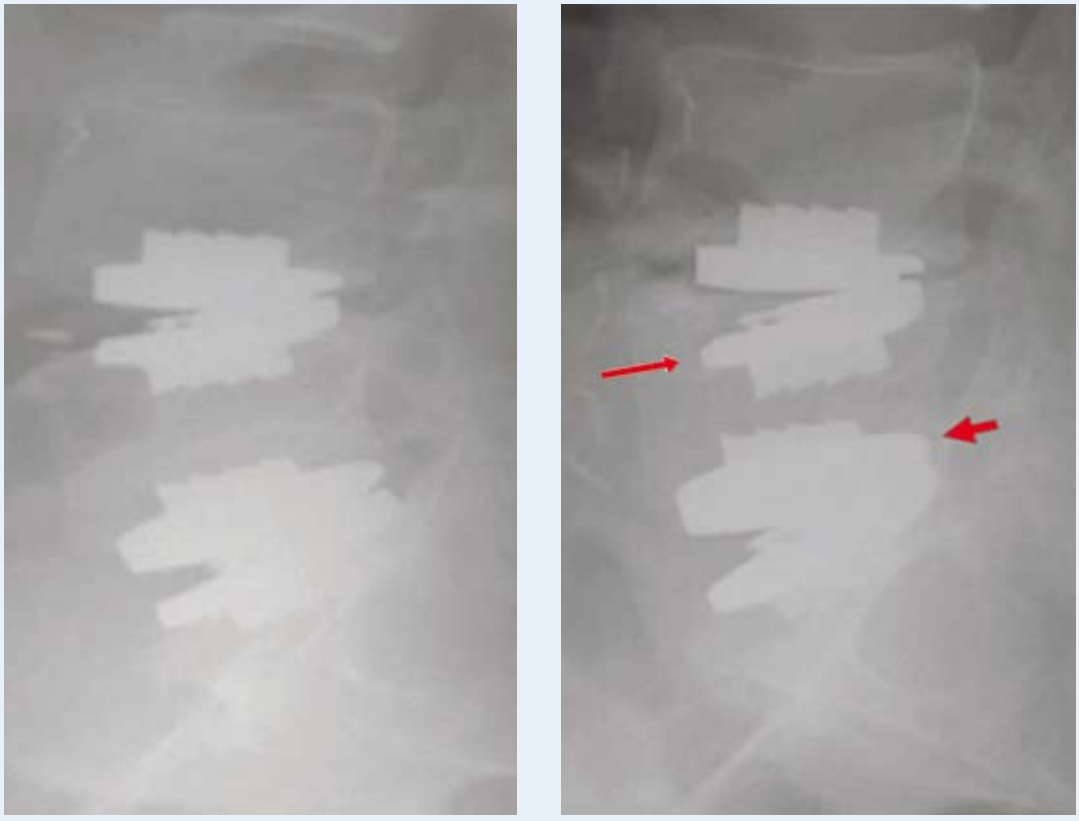

Figure 10: *Because the prostheses do not have shock-absorbing qualities, when two or more level prostheses are used, the vertebra between the prosthesis could easily break, especially if osteoporosis is present (Published with permission of the author [46]).*

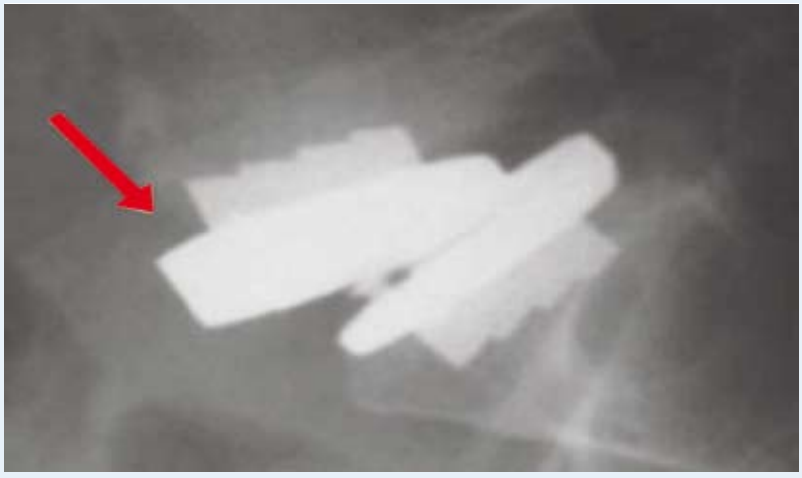

Figure 11: *Especially in the L5-S1 discs, the L5 vertebra is under a severe sliding force and could easily cause the top prosthesis to slip off of the bottom part. An overlooked ischemic effect will shorten this length of time (Published with permission of the author [47]).*

and degenerative scoliosis. As treatment, 22 of these cases underwent posterior fusion. In 24 cases, only the prostheses were removed, and even this group reported increased feeling compared to before surgery. Revision surgery due to TDR complications has a high mortality rate. The main complication is cleaning the connective tissue that forms around major vessels. In reality, in this region in which vital vascular structures are present, a repeat anterior approach is nearly impossible [51]. Major vascular complications are especially observedin discs that have slid forward, and surgery is recommended with a vascular surgeon present. It is almost inevitable for vessels to tear during revision surgery and for post-surgery thrombosis to arise [52].

In a 27-patient series involving complications, van Ooij et al. [37] observed that the major reasons for complaints were degeneration in facet joints and neighboring discs and sliding or embedding of the prosthesis. While acknowledging the rare occurrence of prosthesis breaks, these researchers emphasized the necessity to review disc biomechanics. Because long-term results are not yet published, these researchers stated that only time will tell what complications could develop.

8. Results

Indications of TDR are limited. The correctness of the diagnosis can be suspect, and short term outcomes are similar to those obtained from fusion surgery. There is still doubt as to whether TDR and other non-fusion techniques work without problems. When other joint replacement systems are considered, there is no guarantee as to whether this system will not fail. Revision surgery entails serious risks.

Whereas the May 2004 report published by the Viscolgliosi brothers, who have performed a considerable amount of marketing research in the area of spinal dynamic systems, suggested TDR will peak after 2010 and will become a five-billion-dollar industry, the actual number in 2009 was one billion dollars. Thus, these researchers' prediction has not become reality. Time will tell whether total prostheses, nucleus replacement, or repair will predominate in the future.

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