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DISSERTATION

Comparison of two techniques for denervation of the sacroiliac joint

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List of abbreviations

ASL	anterior sacroiliac ligament
°C	Celsius
COPD	chronic obstructive pulmonary disease
cm	centimeter
CT	computer tomography
Hz	Hertz
ILL	iliolumbar ligament
ISL	interosseus sacroiliac ligament
LPSL	long posterior sacroiliac ligament
min	minute
mm	millimeter
MOS SF-36	Medical Outcome Study Short Form-36
MRI	magnet resonance imaging
ms	milliseconds
NRS	numeric pain rating scale
ODI	Oswestry Disability Index
PSL	posterior sacroiliac ligament
PSNP	posterior sacral nerve plexus
RF	radiofrequency
RMDQ	Roland-Morris Disability Questionnaire
s	second
SD	standard deviation
SIJ	sacroiliac joint
SSL	sacrospinous ligament
STL	sacrotuberous ligament
V	Volt
VAS	visual analog scale
VIPS	visual integer pain
VPS	verbal pain scale

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Abstract

Sacroiliac joint (SIJ) dysfunction is a common cause of lower back pain, affecting 9 – 21% of all chronic back pain patients. Although medical history, pain referral patterns and provocation tests can be indicative of a SIJ syndrome, the current gold standard for diagnosis is a fluoroscopically guided anesthetic block of the joint. Patients should be primarily treated with pain medications and physiotherapy. In case of chronic pain, which is refractory to conservative therapy, radiofrequency denervation is an efficient treatment option. During conventional ablation of the SIJ, several electrodes are inserted targeting fine nerval branches on the dorsal aspect of the sacrum. High interindividual variety in the innervation of the SIJ and distribution of the branches make this procedure challenging. In the last two decades, several variations of this technique were developed to optimize the procedure. One of the most recent methods is denervation using a multi-electrode probe with three electrodes, generating three monopolar and two bipolar fields, thus creating a much larger lesion. Previous studies have proven its safety and efficiency. In this study, we compare conventional ablation of the SIJ and denervation using a multi-electrode probe.

We retrospectively analyzed the clinical outcome of 121 patients, of which 57 received conventional ablation and 64 patients were denervated using the multi-electrode probe. Clinical outcome was measured using the numeric pain rating scale, Oswestry Disability Index, Roland-Morris Disability Questionnaire and Short-Form 36. All patients had follow-up appointments at one, three, six and 12 months after the procedure.

Patients in the multi-electrode probe cohort had stronger and longer lasting pain relief in comparison to the conventional ablation group, with 71.9%, 53.1%, 40.6% and 29.7% of the patients reporting over 50% pain relief at one, three, six and 12 months after the surgery, respectively. In contrast, in the conventional denervation group, this ratio was only 36.8%, 26.3%, 17.5% and 10.5%, respectively. Using the multi-electrode probe also showed a significant benefit over conventional ablation regarding pain-associated disability and health-related quality of life.

Denervation with the multi-electrode probe proved to be a safe and efficient treatment for patients with SIJ pain, with significant advantages over the conventional technique.

Zusammenfassung

Iliosakralgelenk (ISG)-Dysfunktion ist eine häufige Ursache für tiefliegende Rückenschmerzen, woran 9-21% aller Patienten mit chronischen Rückenschmerzen leiden. Anamnese, Schmerzlokalisation und Provokationstests können hinweisend auf ein ISG-Syndrom sein, wobei der aktuelle Goldstandard für die Diagnose eine fluoroskopiegestütze Infiltration des Gelenks mit einem lokalen Anästhetikum ist. Die Behandlung sollte mit Schmerzmedikation und Physiotherapie beginnen. Radiofrequenztherapie ist eine effiziente Therapiemethode bei chronischen Schmerzen, die auf eine konservative Behandlung nicht ansprechen. Bei einer konventionellen ISG-Denervation werden mehrere Elektroden eingebracht um die dünnen Nervenfasern auf der dorsalen Seite des Gelenks zu treffen. Große interindividuelle Unterschiede in der Innervation des ISGs und im Verlauf der einzelnen Fasern machen diesen Eingriff anspruchsvoll. In den letzten zwei Jahrzehnten wurden verschiedene Variationen dieses Verfahrens entwickelt um es zu optimieren. In einer der neuesten Denervationsmethoden wird eine Sonde mit drei Elektroden benutzt, die drei monopolare und zwei bipolare Felder generiert, womit eine deutlich größere Läsion erzeugt werden kann. Bisherige Studien haben die Effektivität und Sicherheit dieser Methode belegt. In dieser Studie vergleichen wir konventionelle Denervierung mit der Denervation mittels einer Multielektroden-Sonde.

Wir haben die klinischen Ergebnisse von 121 Patienten retrospektiv analysiert, 57 Patienten haben eine konventionelle Denervation erhalten, 64 Patienten eine Denervation mittels einer Multi-Elektroden Sonde. Die Ergebnisse wurden anhand der numerischen Schmerz-Bewertungsskala, des Ostwestry-Disability-Indexes, des Roland-Morris Disability Questionnaire und Short-Form 36 erfasst.

Patienten die mit eine Multi-Elektroden Sonde behandelt wurden hatten eine besseren und länger anhaltende Schmerzlinderung verglichen mit dem Patienten die mit eine konventionelle Denervation behandelt wurden. Jeweils 71.9%, 53.1%, 40.6% und 29.7% der Patienten in der Multi-Elektroden Gruppe hatten eine Schmerzlinderung über 50% angegeben nach ein, drei, sechs und 12 Monate nach dem Eingriff. Im Gegensatz dazu war der Anteil dieser Patienten in der konventionellen Denervation-Gruppe jeweils nur bei 36.8%, 26.3%, 17.5% und 10.5%. Die Multi-Elektroden Sonde zeigte auch einen signifikanten Vorteil in Bezug auf durch Schmerzen verursachte Behinderung und auf die Gesundheit bezogene Lebensqualität.

Es konnte bewiesen werden, dass eine Denervation mit der Multi-Elektroden Sonde eine sichere und effiziente Therapieoption für Patientin mit ISG-Syndrom ist mit signifikante Vorteile gegenüber eine konventionelle Denervation.

1. Introduction

1.1. Anatomy of the Sacroiliac joint

The sacroiliac joint (SIJ) is an auricular diarthrodial joint formed between the sacral segments S1 – S3 and the iliac wings (Vleeming *et al.*, 2012). While the sacral part of the joint is concave and more “L”-shaped, the iliac part is convex and “C”-shaped (Brunner, Kissling and Jacob, 1991) (*Fig. 1*). Connecting the spine to the pelvis, and through it to the lower extremities, it is exposed to strong mechanical forces, which requires high stability. This is ensured by interdigitating grooves and ridges on the articular facet and an extended system of supporting ligaments and myofascial structures (Forst *et al.*, 2006). Although the SIJ is not completely rigid, through its structure and the surrounding ligaments, the joint motion is limited to a few degrees of rotation (up to 3.9°) and a few millimeters of translation (up to 1.6 mm) (Sturesson, Selvic and Uden, 1988). There are several qualities that differentiate the SIJ from other diarthrodial joints. For example, the cartilage of the SIJ is not homogenous. While there is thick layer of hyaline cartilage on the sacral side, the iliac side is covered with a much thinner layer of fibrocartilage (Bowen and Cassidy, 1981). Opposed to other diarthrodial joints, the anterior part has the construction of a synovial joint with a clearly definable joint capsule, while the posterior part is more fibrous and the capsule is fused with multiple supporting ligaments (Bowen and Cassidy, 1981; Brunner, Kissling and Jacob, 1991).

Figure 1. *Anatomy of the sacroiliac joint; unpaired sacrum and ilium showing the irregular, "C"-shaped auricular surface of the ilium und "L"-shaped surface of the sacrum. The arrows highlight the iliac tuberosity and the corresponding sacral concavity dorsal to the auricular surface. (With permission from Vleeming et al., 2012).*

There is a large interindividual variety of shape and size of the joint as well as a significant forming process during the development (Solonen, 1957; Bowen and Cassidy, 1981; Dijkstra, Vleeming and Stoeckart, 1989; Brunner, Kissling and Jacob, 1991; Kampen and Tillmann, 1998). While in newborn and children the articular surface is smooth and flat, during the early teenage years the iliac side becomes more convex and the sacral surface correspondingly concave. The joint capsule thickens and becomes more rigid with time, losing its flexibility. The iliac cartilage shows signs of degeneration as early as in puberty, whereas the sacral part is less affected by age-dependent changes (Bowen and Cassidy, 1981; Kampen and Tillmann, 1998). There is also a considerable difference between genders in the structure of the SIJ. The sacrum of women is wider, more uneven, less curved and more backward tilted (Frick, Leonhardt and Starck, 1992) and the S3 segment is rarely completely included into the female SIJ. Furthermore, there are gender-related differences in the size of the supporting ligaments as well (Steinke *et al.*, 2010).

Besides the shape and the specially formed surface of the SIJ, numerous supporting ligaments contribute to the stability of the joint (Vleeming *et al.*, 2012). These can be divided into intrinsic and extrinsic ligaments. The anterior sacroiliac ligament (ASL), the posterior sacroiliac ligament (PSL), the interosseus sacroiliac ligament (ISL) and the long posterior sacroiliac ligament (LPSL) form the intrinsic system, while the iliolumbar ligament (ILL), the sacrotuberous ligament (STL) and the sacrospinous ligament (SSL) form the extrinsic network (Poilliot *et al.*, 2019). The strongest and biggest of these ligaments is the interosseous sacroiliac ligament, providing stability especially during flexion and axial rotation (Steinke *et al.*, 2010; Eichenseer, Sybert and Cotton, 2011).

Muscles also add to the stiffness and stability of the SIJ. In particular, the biceps femoris, the gluteus maximus and the erector spinae seem to support to the rigidity of the joint (Van Wingerden *et al.*, 2004).

The innervation of the SIJ is complex. There are interindividual differences regarding which spinal nerves are involved and the course of their branches. The posterior SIJ is innervated by the lateral branches of posterior rami of S1 – S3 (Horwitz, 1939; Roberts *et al.*, 2014) and irregularly by L5 and S4. While the cranial dorsal part of the joint seems to be solely innervated by branches of S1, the innervation of the medial and inferior part is provided by a fine nerve plexus, called the posterior sacral nerve plexus (PSNP), on the posterior surface of the joint. The PSNP spreads between the sacral foramina and the interosseous sacroiliac ligament. While the medial part is on periosteal level, the lateral part spreads on the supporting ligaments and penetrates the interosseous ligament to reach the joint (Roberts *et al.*, 2014). The anterior aspect of the SIJ is innervated by the ventral rami of L4 – S2, and irregularly by L3 (Solonen, 1957; Poilliot *et al.*, 2019). The cranial part of the anterior SIJ is mainly innervated by L5, while for the caudal part it is primarily by S2 and branches from the sacral plexus.

1.2. SIJ dysfunction

Back pain is one of the most common symptoms in the adult population, affecting around 85% of the German population in their lifetime (Schmidt *et al*, 2007). About 19% of the population develops chronic back pain, defined by symptoms persisting for 3 months or longer (Neuhauser, Ellert and Ziese, 2005). Studies using fluoroscopically guided injection of local anesthetic in the SIJ estimated that about 9 to 21% of chronic lower back pain originates from the SIJ (Schwarzer, Aprill and Bogduk, 1995; Maigne, Aivaliklis and Pfefer, 1996). SIJ syndrome mainly affects patients around their fifties and sixties, and more frequently women than men (Chou *et al.*, 2004; Irwin *et al.*, 2007; DePalma, Ketchum and Saullo, 2011; Cher, Polly and Berven, 2014).

SIJ pain substantially compromises quality of life. Patients with SIJ syndrome report higher burden from the disease than patients with other serious medical conditions such as chronic obstructive pulmonary disease (COPD), coronary heart disease or asthma. According to patients' subjective assessment, the impact of SIJ pain on their life quality is similar to the one reported by patients with chronic depression or severe COPD (Cher, Polly and Berven, 2014).

The sources of SIJ pain can be split into intraarticular and extraarticular causes (Cohen, Chen and Neufeld, 2013). Common intraarticular etiologies are spondyloarthropathies and arthritis (Luukkainen *et al.*, 1999), while injuries of the supporting ligaments, muscles and entheses are considered as extraarticular origins. In many non-rheumatological cases the onset of SIJ syndrome can be traced back to an inciting event, such as trauma or persistent overstraining (Chou *et al.*, 2004), but additionally back surgery, particularly lumbar or lumbosacral fusion, can cause SIJ dysfunction (Liliang *et al.*, 2011). Further important risk factors are leg length discrepancy, gait abnormalities and pregnancy (Cohen, 2005). However, there is still a high number of idiopathic cases.

Medical history and pain referral pattern are not reliable in the diagnosis of SIJ syndrome. There is a variety of pain patterns that are characteristic for these patients, and for most patients suffering from pain in the lower back, the gluteal region or in the groins (Slipman *et al.*, 2000; Jung *et al.*, 2007). Depending on whether one or both SIJs are involved, the pain pattern might be symmetrical or one-sided. Pain at or around the posterior superior iliac spine (PSIS) seems to be more characteristic for pain originating from the SIJ (Murakami, Kurosawa and Aizawa, 2018). In about half of the patients, the pain radiates into the lower extremities, most frequently into the thighs (Slipman *et al.*, 2000). Generally, pain above the fifth lumbar vertebra and midline pain are atypical for patients with SIJ syndrome (Dreyfuss *et al.*, 1996; DePalma *et al.*, 2011). There is no evidence that exaggeration of the pain through activities like sitting, standing or walking would be reliable indicators (Dreyfuss *et al.*, 1996). The variety of pain patterns could be explained by the involvement of different parts of the SIJ (Kurosawa, Murakami and Aizawa, 2015) and the irritation of the surrounding neural structures (Fortin *et al.*, 1999; Fortin, Vilensky and Merkel, 2003). A study by Fortin et al. (2003) showed leakage of intraarticularly injected contrast medium dorsally, ventrally and superiorly in SIJ pain patients. Furthermore, they proved the presence of intraarticular substance P in SIJ pain patients, which, along with other inflammatory mediators, can provoke pain in nearby structures. According to their findings, especially the lumbosacral plexus, the first sacral nerve root and the fifth lumbar spinal nerve can be affected.

The role of provocation tests is controversial. While none of the tests seem to be solely efficient for diagnosis (Dreyfuss *et al.*, 1996), the combination of 3 or more test achieves a moderate sensitivity and specificity (Laslett *et al.*, 2005; Van Der Wurff, Buijs and Groen, 2006). Laslett et al. (2005) described an optimal combination with the distraction, thigh thrust, compression and sacral thrust tests, whereby the examination is conclusive after two positive tests. The provocation tests are described in Table 1.

Radiological diagnosis is only used for the exclusion of important differential diagnoses in the assessment of SIJ pain (Vanelderen *et al.*, 2010). Magnet resonance imaging (MRI) can be used to differentiate between acute inflammation and chronic destruction, for example in the context of sacroiliitis (Puhakka *et al.*, 2004). Computer tomography (CT) scans show a very low sensitivity and specificity for SIJ dysfunction (Elgafy *et al.*, 2001). Although radionuclide imaging has a high specificity, there is a high percentage of false-negative results (Slipman *et al.*, 1996; Maigne, Boulahdour and Chatellier, 1998).

The current golden standard for the diagnosis of SIJ pain is fluoroscopically guided, contrast enhanced, dual comparative local anesthetic block (Simopoulos *et al.*, 2012). However, as this is an invasive procedure with associated risks, such as sciatic palsy (Van Der Wurff, Buijs and Groen, 2006), it is only performed in patients without sufficient response to conservative therapy. It is controversial as to what degree of pain relief is considered to be a positive test result (Szadek *et al.*, 2009). In some patients, periarticular injections seem to have a stronger effect than intraarticular injections, which highlights the role of the surrounding ligaments, muscles and enthuses in the etiology of SIJ pain (Murakami *et al.*, 2007; Murakami, Kurosawa and Aizawa, 2018).

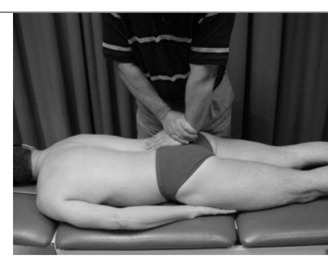
Tests	Description	Illustration
Distraction	The patient is in supine position while the examiner applies pressure on both anterior superior iliac spines at the same time (*Fig. 2*).	 Figure 2. *Distraction test*
Thigh thrust	The patient is in supine position, the leg on the contralateral side extended. The hip and the knee are flexed on the affected side, with the thigh at a right angle to the table. The examiner holds the sacrum with one hand and wraps the other hand around the knee. He applies pressure along the long axis of the femur while slightly adducting the thigh (*Fig. 3*).	 Figure 3. *Thigh thrust test*
Gaenslen's test	The patient is in supine position on the contralateral side, close to the edge of the table. The leg on the unaffected side hangs over the edge of the table, the hip and the knee are flexed on the other side. The examiner puts pressure on the knee, flexing it towards the patient's chest while pushing the other knee towards the floor (*Fig. 4*).	 Figure 4. *Gaenslen's test*
Compression	The patient lies on the unaffected side with the back towards the examiner. Hips are flexed to ca. 45°, knees are flexed to about a right angle. The examiner applies downward pressure on the anterior edge of the iliac crest (*Fig. 5*).	 Figure 5. *Compression test*
Sacral thrust	The patient lies on their stomach with both legs extended. The examiner puts downward pressure on the central sacrum (*Fig. 6*).	 Figure 6. *Sacral thrust test*

Table 1. *Common provocation test used to diagnose SIJ pain* (Kokmeyer *et al.*, 2002; Laslett *et al.*, 2003) *(All figures with permission from Laslett et al., 2005)*

1.3. Therapy

There are several treatment options for SIJ pain, including both conservative and invasive therapies. In the acute phase therapy should include analgesics, such as nonsteroidal anti-inflammatory drugs, icing and relative rest (Prather and Hunt, 2004; Foley and Buschbacher, 2006; Forst *et al.*, 2006; Schenker *et al.*, 2019). In the subsequent recovery phase, the joint should be gradually mobilized. After restoring muscle length with the help of flexibility exercises, muscle strength should be built up to support the joint and correct the biomechanical imbalance. SIJ belts can increase stability in patients with hypermobility or muscle weakness, and are a very important tool for treating pregnant patients, for whom the use of drugs and invasive therapy should be avoided (Prather and Hunt, 2004; Foley and Buschbacher, 2006). In case of anatomical leg length discrepancy, a shoe lift should be fitted for the patient. If the symptoms can be traced back to a rheumatological disease, the drug therapy should be optimized (Schenker *et al.*, 2019).

Aside from their diagnostical function, fluoroscopically or CT-guided injections can also be used as therapy. Longer lasting pain relief can be achieved by the additional use of corticosteroids (Maugars *et al.*, 1996; Berthelot *et al.*, 2006; Foley and Buschbacher, 2006; Rashbaum *et al.*, 2016). There seems to be no significant difference between the outcome after intra- or periarticular injections, which highlights the effectiveness of a dorsal rami block as a treatment for SIJ pain (Luukkainen *et al.*, 2002; Hartung *et al.*, 2010; Nacey, Patrie and Fox, 2016). Further studies have been carried out to analyze the benefits of intraarticular injections with other agents. Phenol, a neurolytic medication, can provide a prolonged pain relief (Ward *et al.*, 2002). However, due to the frequent presence of tears in the joint capsule (Fortin, Vilensky and Merkel, 2003), it carries a relatively high risk of affecting nearby neural structures (Cohen, Chen and Neufeld, 2013). Additionally, studies with a limited amount of subjects have been carried out to investigate injections with hyaluronic acid, with promising results (Srejic, Calvillo and Kabakibou, 1999).

Another therapy option is radiofrequency (RF) denervation. During conventional RF ablation of the SIJ, multiple electrodes are inserted and fluoroscopically guided, targeting branches of the lumbosacral spinal nerves innervating the dorsal aspect of the joint (Cohen, Chen and Neufeld, 2013; Roberts *et al.*, 2018). An electrical field is induced, generating heat reaching 60-80°C, which causes a lesion in the surrounding tissue and nerve branches (Smith, McWhorter and Challa, 1981; Cosman and Cosman, 2005; Aydin *et al.*, 2010). This method produces a small lesion with an approximately 3-4 mm diameter horizontally (Cohen *et al.*, 2009; Cohen, Chen and Neufeld, 2013; Roberts *et al.*, 2018), thus the correct positioning of the electrodes is crucial. A better outcome can be reached through sensory stimulation before lesioning (Yin *et al.*, 2003). In this technique, several lesions are produced at each level, in some studies only targeting S1-S3 (Yin *et al.*, 2003), in others including L4 and L5 (Cohen and Abdi, 2003; Cheng *et al.*, 2012; Romero *et al.*, 2015) (*Tab. 2*). For the sacral levels, the electrodes are placed at the lateral edge of the sacral foramina.

Considering the interindividual differences in the anatomical distribution of the fine lateral branches innervating the SIJ, another option to improve the outcome is to increase the size of the lesion. This can be achieved with different techniques. For example, by producing a bipolar field using two or more electrodes, a much larger lesion can be achieved (Cosman Jr. and Gonzalez, 2011). Burnham & Yasui (Burnham and Yasui, 2007) performed this technique, producing strip lesions around the lateral half of the sacral foramina, while Ferrante (Ferrante *et al.*, 2001) produced strip lesions along the posterior margin of the joint. Although the criteria for successful outcome was not identical in these two studies, Burnham & Yasui (2007) reported a much higher rate of patient satisfaction (*Tab. 2*).

A further option to increase the size of the lesion is cooled RF ablation. During this procedure, the electrode is cooled internally, which keeps the temperature of the electrode and the surrounding tissue relatively low (Ho *et al.*, 2013). This technique prevents the formation of a coagulum; therefore the impedance stays low, creating a lesion measuring about 8-10 mm in diameter (Watanabe *et al.*, 2002; Roberts *et al.*, 2018). Two placebo-controlled studies were performed to assess the efficiency of the procedure, with good results after 6 and 9 months, respectively (Cohen *et al.*, 2008; Patel *et al.*, 2012). However, no significant difference has been found between cooled and conventional RF denervation regarding the clinical outcome (Cheng *et al.*, 2012) (*Tab. 2*).

Vallejo et al. (Vallejo *et al.*, 2006) researched pulsed RF ablation for SIJ pain. In this procedure, RF signals are delivered into the surrounding tissue with a pulse duration of about 10-30 ms and a repetition frequency of 1 to 8 Hz (Cosman and Cosman, 2005). This technique also prevents high temperatures and the formation of a coagulum. The results showed a significant pain relief lasting up to 6 months post intervention; however, this is the only study that has been conducted with this technique, and it had a limited number of participants (*Tab. 2*).

A relatively new RF denervation technique is performed with a multi-electrode radiofrequency probe (Simplicity III RF probe, Abbott Medical GmbH), with 3 active areas and a curved design for easier positioning (Schmidt, Pino and Vorenkamp, 2014; Anjana Reddy *et al.*, 2016; Bellini and Barbieri, 2016; Gilligan *et al.*, 2016). This probe creates 3 monopolar lesions around the active areas and 2 bipolar lesions between them, forming one long strip lesion with the size of 9 x 52.5 mm (Schmidt, Pino and Vorenkamp, 2014; Gilligan *et al.*, 2016) (*Fig. 7*). The probe is placed under fluoroscopic guidance lateral to the sacral foramina along the long axis, covering the lateral branches of S1-S4. One advantage of this procedure is that there is only a single entry point, reducing post-operative patient discomfort due to skin lesion and risk of infection. Furthermore, it produces a relatively large lesion, which should include most of the lateral branches despite anatomical variability. Several studies have been performed to assess the outcome after RF ablation with this multilesion probe, with more favorable or similar results compared to previous studies with other RF techniques (Schmidt, Pino and Vorenkamp, 2014; Anjana Reddy *et al.*, 2016; Bellini and Barbieri, 2016; Hegarty, 2016) (*Tab. 2*).

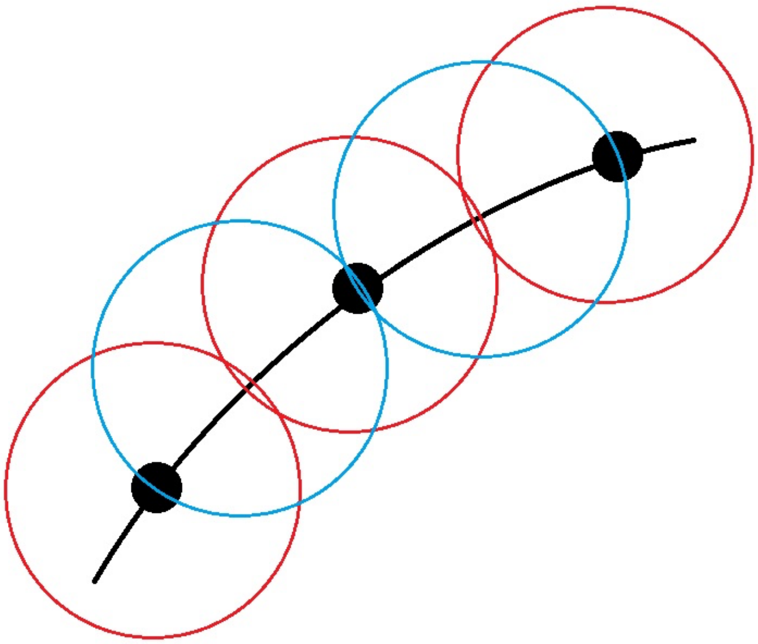


Figure 7. *Schematic representation of the design of the multi-electrode RF probe: three electrodes are represented by black dots, three monopolar lesions are represented by red circles and two bipolar lesions are represented by blue circles.*

For patients with SIJ pain refractory to conservative therapy or minimally invasive denervation, arthrodesis should be considered. Minimally invasive surgery techniques for SIJ fusion appeared in the early 2000s (Al-Khayer *et al.*, 2008; Wise and Dall, 2008), which offered a safer option to open surgery, with lower blood loss, shorter surgeries and shorter hospital stay (Smith *et al.*, 2013; Ledonio, Polly and Swiontkowski, 2014) (*Fig. 8*).

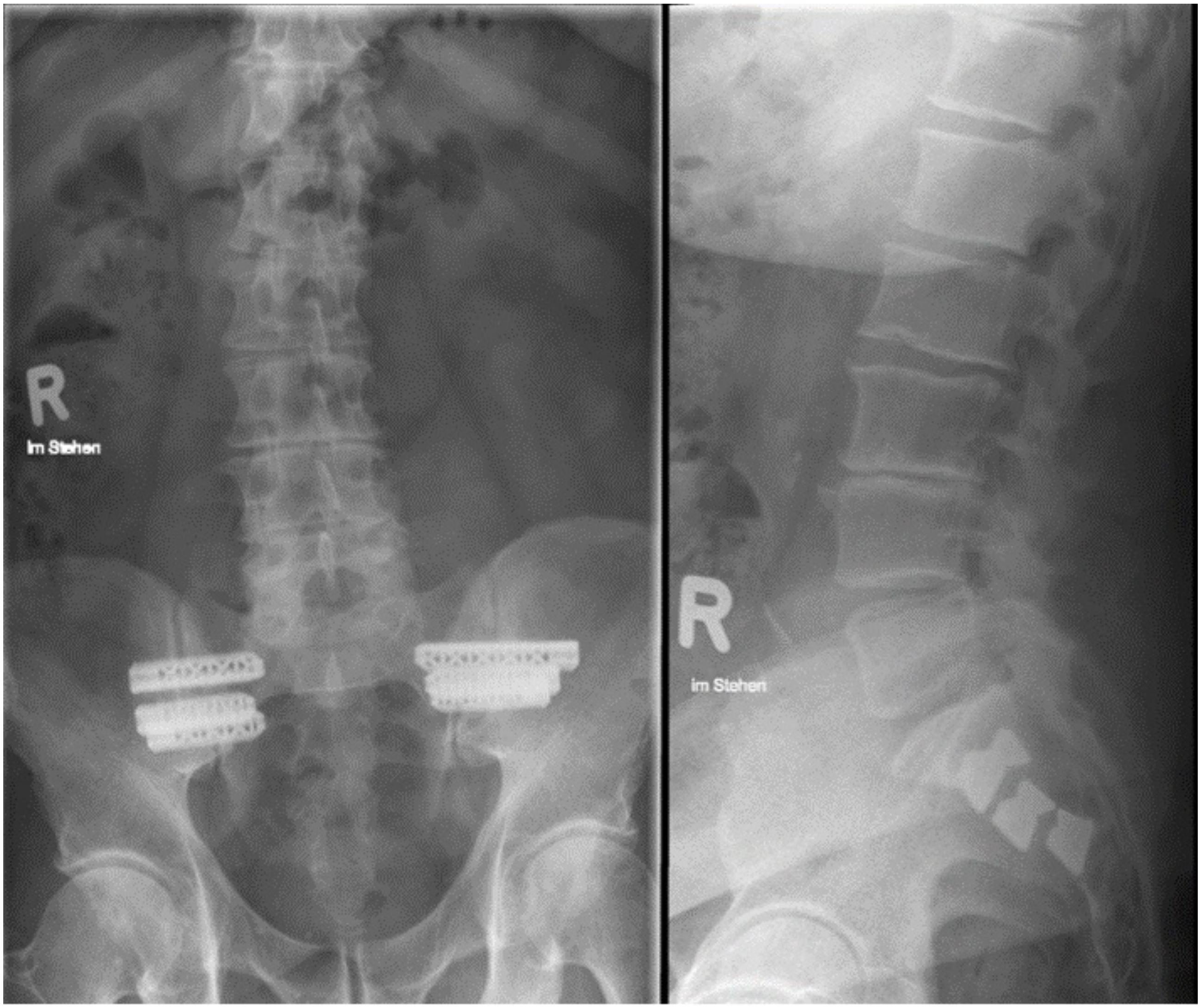


Figure 8. *Representative anterior-posterior and lateral X-ray images after minimally invasive SIJ fusion.*

	Study	Sample	Primary outcome measurement	Results
Conventional RF	Cohen & Abdi (2003)	18 patients, 9 receiving RF	>50% reduction in VAS after 9 months	8 out of 9 patients with positive results
	Yin et al. (2003)	14 patients	>60% reduction in VIPS and >50% subjective pain relief after 6 months	64% successful outcome
	Romero et al. (2015)	32 patients	NRS difference after 18 months	Decrease from 7.7 ± 1.8 to 4.0 ± 2.7
Bipolar RF	Burnham & Yasui (2007)	9 patients	NRS difference after 12 months	NRS decrease in median -4.1
	Ferrante et al. (2001)	33 patients	>50% reduction in VAS after 6 months	36.4% successful outcome
Cooled RF	Cohen et al. (2008)	28 patients, 14 RF, 14 placebo, 11 crossover	NRS difference after 6 months	NRS reduced 57% in RF group. 52% in crossover group (after 3-months insufficient subject number in placebo group)
	Patel et al. (2012)	50 patients, 34 RF, 17 placebo	>50% reduction in NRS after 3 months	47% in RF-group, 12% in placebo group
	Cheng et al. (2012)	88 patients, 30 conv. RF, 58 cooled RF	>50% reduction in NRS after 12 months	No significant difference
	Ho et al. (2013)	20 patients	NRS difference after 2 years	Decrease from 7.4 ± 1.4 to 3.1 ± 2.5
Pulsed RF	Vallejo et al. (2006)	22 patients	Good if >50%, excellent if >75% reduction in VAS	Good or excellent lasting on average 20 ± 5.7 weeks
Simplicity	Schmidt et al. (2014)	77 patients	>50% reduction in VPS after 6 months and 1 year	54.4% positive outcome after 6 months, 15.6% after 1 year
	Anjana Reddy et al. (2016)	26 patients, 10 dropouts	NRS reduction after 12 months	Decrease from 8.8 to 4.3 after 1 year
	Bellini et al. (2016)	60 patients	ODI after 1, 3, 6 months and 1 year	Decrease from 64 ± 4.3 to 43 ± 2.2 after 3 months and 12 ± 3.5 after a year
	Hegarty (2016)	11 female patients	Reduction in VAS after 12 months	Decrease from 7.7 to 3.0

RF: radiofrequency, VAS: visual analog scale, VIPS: visual integer pain scale, NRS: numeric pain rating scale, VPS: verbal pain scale, ODI: Oswestry Disability Index

Table 2. *Main results of studies on different type of radiofrequency denervation*

2. Objective

Although several studies have been performed to analyze different therapy options for recurring SIJ pain, there are no official guidelines. RF denervation is a minimally invasive, safe procedure which has proven to provide lasting pain relief for up to a year (Cohen, Chen and Neufeld, 2013). However, there are several different techniques and only a few studies that have compared them. Studies investigating the efficiency of multilesion RF probes showed significant pain relief lasting for several months, and also improvement in quality of life and functionality (Anjana Reddy *et al.*, 2016; Bellini and Barbieri, 2016; Hegarty, 2016). This study aims to compare the clinical outcome for patients after RF denervation with a multi-electrode probe and conventional monopolar RF denervation over a one year period.

3. Methods

3.1. Subjects

We retrospectively analyzed the clinical data of 156 patients between the ages of 27-88 years who received isolated RF denervation of the SIJ from 2011 to 2016. All patients presented with pain in the typical areas in the lower back and the gluteal region. Only patients with chronic SIJ pain refractory to conservative treatment with anti-inflammatory medication, as well as to physical and manual therapy, were considered for RF denervation. Other differential diagnoses for lower back pain or gluteal pain were reasonably excluded based on medical history, physical examination, radiological diagnostics (CT, MRI or myelography) or diagnostic anesthetic nerve blocks. The diagnosis was confirmed by fluoroscopically guided, contrast enhanced intraarticular injections with local anesthetics (either 5 mg bupivacaine hydrochloride or 20 mg mepivacaine hydrochloride) and corticosteroids (40 mg triamcinolone). All patients attended a follow-up appointment one year after the intervention at our outpatient clinic. The result for the infiltration was rated positive if the pain relief was greater than 50% on the visual analog scale (VAS). Patients who received surgery of the lumbar spine or SIJ or further invasive treatment of the SIJ within 6 months following the denervation were excluded from the study. If the RF denervation was repeated, only the clinical results of the second denervation were included in this study.

The ethical approval for this was given by the local ethics committee, reference number EA2/093/13.

3.2. Denervation techniques

3.2.1. Conventional monopolar RF ablation

Conventional monopolar RF denervation was performed as an ambulatory procedure under minimal or moderate sedation. Patients were placed into prone position. The SIJ and the sacral foramina were fluoroscopically presented with a C-arm in oblique projection. For targeting the dorsal ramus of the L5, the sulci between the superior articular process of the first sacral vertebra and the sacral ala were identified. For the lateral branches of S1 to S3, the sacral foramina were identified, targeting about 1 to 3 mm laterally from the lateral edge of each foramina. Sterile washing and covering followed, according to the hospital's standards. After infiltrating the skin with a local anesthetic at the entry points, an 18-gauge, 100 mm long cannula was subsequently inserted at each target point. After injecting either 5 mg bupivacaine hydrochloride or 20 mg mepivacaine hydrochloride as a local anesthetic, a motor stimulation was performed at 2 Hz and up to 1.5 V, to avoid the involvement of motoric fibers of the ipsilateral lower extremity. After conforming the correct position of the cannula, RF denervation was performed for 60 s at 85°C using the NeuroN50 system (inomed Medizintechnik GmbH, Emmendingen, Germany).

3.2.2. Denervation with multi-electrode RF probe

RF denervation with the multilesion probe (Simplicity III RF probe, Abbott Medical GmbH) was performed under general anesthesia as an inpatient procedure. Patients were placed into prone position. The SIJ joint was displayed using two C-arms, one of them with anterior-posterior projection, and the other one for the lateral view. After sterile washing and covering, the percutaneous entry point was identified 1 cm laterally and caudally from the S4 foramina. Local anesthesia was applied subcutaneously at the entry point. Subsequently, the multi-electrode probe was inserted, positioned laterally to the foramina and medially to the SIJ, as close to the periosteum as possible, with the curve of the electrode following the shape of the posterior surface of the sacrum. A safe distance from the dermis was kept, so as to avoid skin injury. The three active contacts were placed corresponding to S1-S3. The position of the probe was confirmed using both C-arms. Consecutively, motor stimulation was performed at 2 Hz and up to 3 V at each contact separately to test for the involvement of motoric fibers. Denervation was performed at 80-85°C for 60 seconds, initially creating monopolar lesions around each contact, followed by generating bipolar fields between the contacts separately, which finally created 3 monopolar and 2 bipolar lesions. The NT110 system (*Abbott*, IL, USA) was used for this procedure.

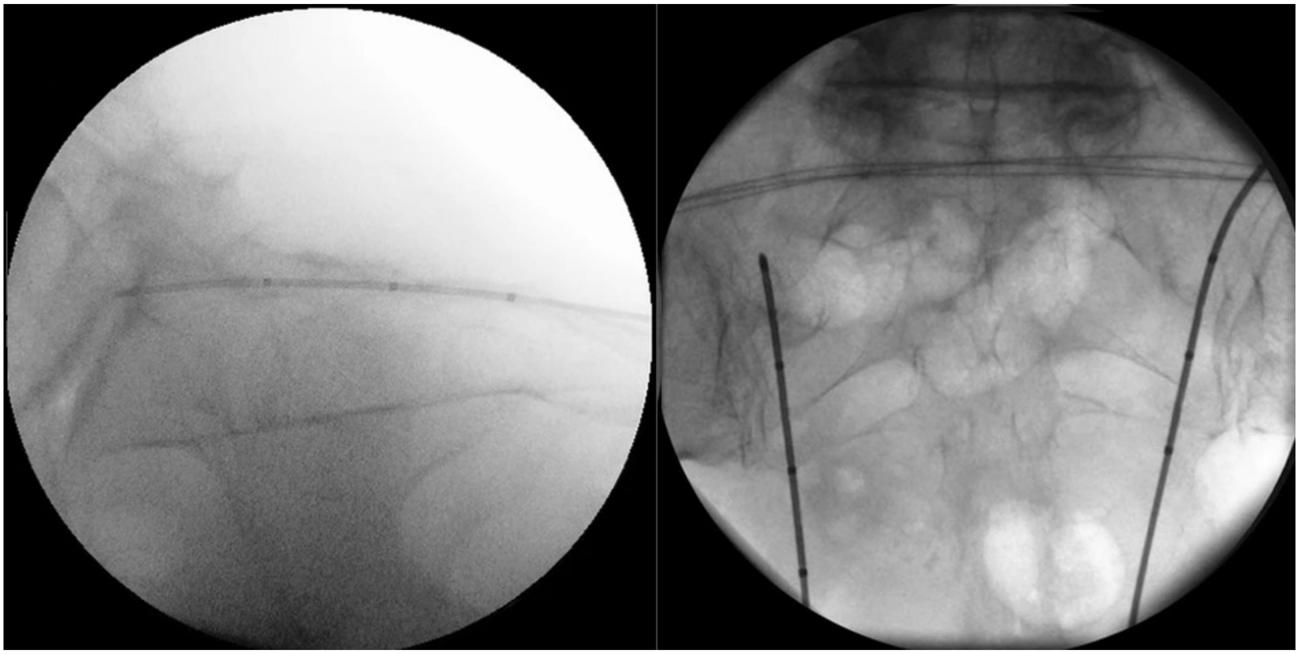


Figure 9. *Representative lateral and anterior-posterior X-ray images after final positioning of the multi-electrode probe. (With permission from Bayerl et al., 2020)*

3.3. Patient-reported outcome measures

The primary outcome for this study was pain relief, measured on the numeric pain rating scale (NPRS). Patients were invited for outpatient appointments one, three, six and 12 months after the procedure, according to the standard follow-up care of the clinic. Before the surgery, and at the follow-up appointments, patients were examined by one of the physicians and they were asked to fill out questionnaires about their functional disability and life quality. Functional disability was evaluated using the Oswestry Disability Index (ODI) and the Roland-Morris Disability Questionnaire (RMDQ). A Medical Outcome Study Short Form-36 (MOS SF-36) questionnaire was used to assess health-related quality of life. Subjective satisfaction with the procedure was documented using Odom's criteria one year after surgery.

3.3.1. NPRS

NPRS is a scale to measure the intensity of perceived pain. It ranges from 0 to 10, 0 meaning no pain at all and 10 meaning the worst imaginable pain. Its advantage is that it gives a quick, easily understandable and comparable assessment of the current status of the patient, which is very important in a clinical setting. However, the information gained is very limited (Kahl and Cleland, 2005).

3.3.2. ODI and the RMDQ

The ODI and the RMDQ are the most commonly used evaluation forms for clinical outcome and progress in patients with spinal disorders (Roland and Fairbank, 2007). The advantage of these questionnaires is that they provide a quick assessment and have a simple scoring system. Furthermore, these questionnaires show good reliability and are sensitive for detecting clinically relevant changes (Roland and Fairbank, 2007).

The ODI is split into 10 different sections, analyzing various aspects of daily life that can be compromised by backpain (personal hygiene, lifting, walking, standing, sitting, sleeping, sexual life, social life and travelling). In each section, the patients can choose how strongly they are affected by their pain on a scale of 6 statements. The answers should represent their current state of functionality. In this study, the German translation of a modified version of the ODI (2.1a) was used, which was introduced by Mannion et al. (2006) (Fairbank and Pynsent, 2000; Mannion *et al.*, 2006).

The RMDQ is a questionnaire with 24 items, where the patients are required to choose the statements that apply to their current state of functionality. These statements were selected from the health status questionnaire Sickness Impact Profile (Bergner *et al.*, 1981) and adapted so that they would specifically apply to disability caused by backpain. In this study, we used the German translation published by Wiesinger et al (1999) and Exner & Keel (2000) with minor modifications.

Studies comparing ODI and RMDQ have shown the similar qualities of these questionnaires, with none of them showing significant advantages over the other (Roland and Fairbank, 2007; Chiarotto *et al.*, 2016). However, it seems that ODI is a better instrument to show changes in patients with high level of disability, while RMDQ is a better fit for patients with lower disability levels (Roland and Fairbank, 2007).

3.3.3. MOS SF-36

Since its development in 1992, the MOS SF-36 has become a widely used to tool to assess health-related life quality for diverse patients groups (McHorney, Ware and Raczek, 1993; Mallinson, 2002). This questionnaire is constructed of 36 items, each assessing one the following aspects of life quality: physical functioning, limitations in daily life because of physical problems, somatic pain, social functioning, mental health, limitations in daily life because of psychological difficulties, vitality, and the general subjective perception of one's own health (Ware and Sherbourne, 1992). The questions are phrased in a way where their use is not limited to a special patient group or a specific disease. MOS SF-36 has a high test-retest reliability and internal consistency. Furthermore, it is more sensitive to minor health problems than other health status questionnaires (Brazier *et al.*, 1992).

The number of possible answers range from 2 to 6 for each item. Scores can be either calculated for each life quality aspect or summarized as mental and physical health related life quality. The results are calculated according to the Likert method (Likert, 1932) and range from 0 to 100, with higher scores meaning a better quality of life. In this study we summarized the answers into a score for mental- and a score for physical health related quality of life.

3.4. Intraoperative parameters

Operation time was documented in minutes (min) and was defined as the time from applying local anesthesia till the removal of the last probe. Fluoroscopic exposure times were documented in seconds (s).

3.5. Statistical analysis

All data was collected using Microsoft Excel (Microsoft Corporation, Redmond, WA, USA). The statistical evaluation and graphical presentation were performed with SPSS (IBM Corp., Released 2020. IBM SPSS Statistics for Macintosh, Version 27.0. Armonk, New York, NY, USA). For each parameter normal distribution was calculated using the Kolmogorov–Smirnov test. To compare basic characteristics and clinical outcome between the two groups, the Student’s t-test was used for normally distributed parameters, and the Mann-Whitney U test was performed when normal distribution could not be assumed. To compare values at different points in time within the groups, the Friedman test was performed. Post-hoc analysis was conducted using the Dunn-Bonferroni test. P values under 0.05 were considered significant.

4. Results

4.1. Baseline characteristics

Out of the 156 patients, 121 could be included in this study. 26 patients were excluded because they did not attend the follow-up appointments regularly, mainly because of their long commute. 9 patients could not be contacted after the procedure, whether by telephone or mail.

All patients treated for chronic SIJ pain with RF denervation before November 2013 received the procedure according to the conventional, monopolar technique. From November 2013, all SIJ syndrome patients admitted for RF ablation received denervation using the multilesion probe. 57 patients received conventional RF denervation, 17 bilaterally and 40 unilaterally. 64 patients received denervation using the multi-electrode RF probe, 22 bilaterally and 42 unilaterally.

The mean age in the group for conventional RF ablation was 58 years (±14.4), the youngest patient being 29 and the oldest 86 years old. In the multi-electrode RF group, the mean age was 60 years (±15.6), the youngest patient being 27 and the oldest 88 years old. In both groups, women were more represented than men. In the conventional RF ablation group the ratio of men to women was 14 to 43, and in the multi-electrode denervation group 19 to 45. 17 out of the patients in the conventional RF group had prior spine surgery, as compared to 20 patients in the multi-electrode RF group.

		Conventional RF ablation (N = 57)	Multi-electrode RF ablation (N = 64)	p Value
Age Years (SD)		Mean 58 (±14.4) Median 57	Mean 60 (±15.4) Median 61	p = 0.42
Female sex (%)		43 (75.4)	45 (70.3)	
Denervation (%)	Bilateral	17 (29.8)	22 (34.4)	
	Unilateral	40 (70.2)	42 (65.6)	
Prior spine surgery (%)		17 (29.8)	20 (31.3)	
Mean NPRS (SD)		7.7 (±1.5)	8.0 (±1.2)	p=0.41
Mean RMDQ (SD)		15.4 (±4.8)	16.4 (±3.3)	p=0.93
Mean ODI (SD)		25.8 (±4.8)	25.9 (±5.2)	p=0.84
Mean MOS SF-36 (SD)		27.9 (±5.9)	28.6 (±6.6)	p=0.55

Table 3. *Baseline data of both groups*

The mean pain level, measured on the NPRS prior to the procedure, was 7.7 (±1.5) in the conventional RF group and 8.0 (±1.2) in the multi-electrode group, showing no significant difference between the two groups (p=0.27). Similarly, there was no significant difference in the initial RMDQ scores; in the conventional RF group the mean RMDQ score prior to the procedure was 15.4 (±4.8), and in the multi-electrode RF group 16.4 (±3.3) (p=0.22). There was no significant difference in the initial ODI score either; the mean score for patients in the conventional RF group was 25.8 (±4.8), and in the multi-electrode RF group it was 25.9 (±5.2). The mean score for physical health related life quality prior to the surgery, measured with MOS SF-36, was 27.9 (±5.9) in the conventional RF group and 28.6 (SD±6.6) in the multi-electrode RF group, with no significant difference between groups (*Tab. 3*).

4.2. Clinical outcome

4.2.1. NPRS

Patients in the conventional RF group significantly benefited from the intervention in terms of pain relief ($\chi^2_F(4)=113.4$, $p<0.001$, N=57). In this group, the mean NPRS score was the highest pre-intervention (7.7± 1.5), and the lowest was one month post-intervention (5± 2.3). During the following months there was a steady increase in the mean NPRS scores to 5.5 (±2.1) after three months, 6.1 (±2.1) after six months, and 6.4 (±1.9) after 12 months. However, the post-hoc analysis still showed a significant difference between the NPRS scores prior to the intervention and after one year (z=0.93, p=0.017).

The mean NPRS scores in the multi-electrode group also showed a significant difference over time ($\chi^2_F(4)=173.3$, $p<0.001$, N=64) with a similar dynamic. In this group, the mean NPRS was 8.0 (±1.2) prior to the intervention, and then decreased to 3.5 (±2.3) after one month (z=2.88, p<0.001). The mean score was 4.4 (±2.5) after three months, 5.1 (±2.3) after six months, and 5.6 (±2.2) after 12 months. The post-hoc analysis also showed significant differences when comparing the mean score prior to the intervention with the results after three months (z= 2.29, p<0.001), after six months (z=1.49, p<0.001), and after 12 months (z=0.95, p=0.006).

Comparing both groups, denervation with the multi-electrode probe showed a significant advantage over conventional RF denervation at one month (U=1115.5, p<0.001), three months (U=1283, p=0.005), six months (U=1335.5, p=0.011), and 12 months (U=1433, p=0.041) (*Fig. 9*).

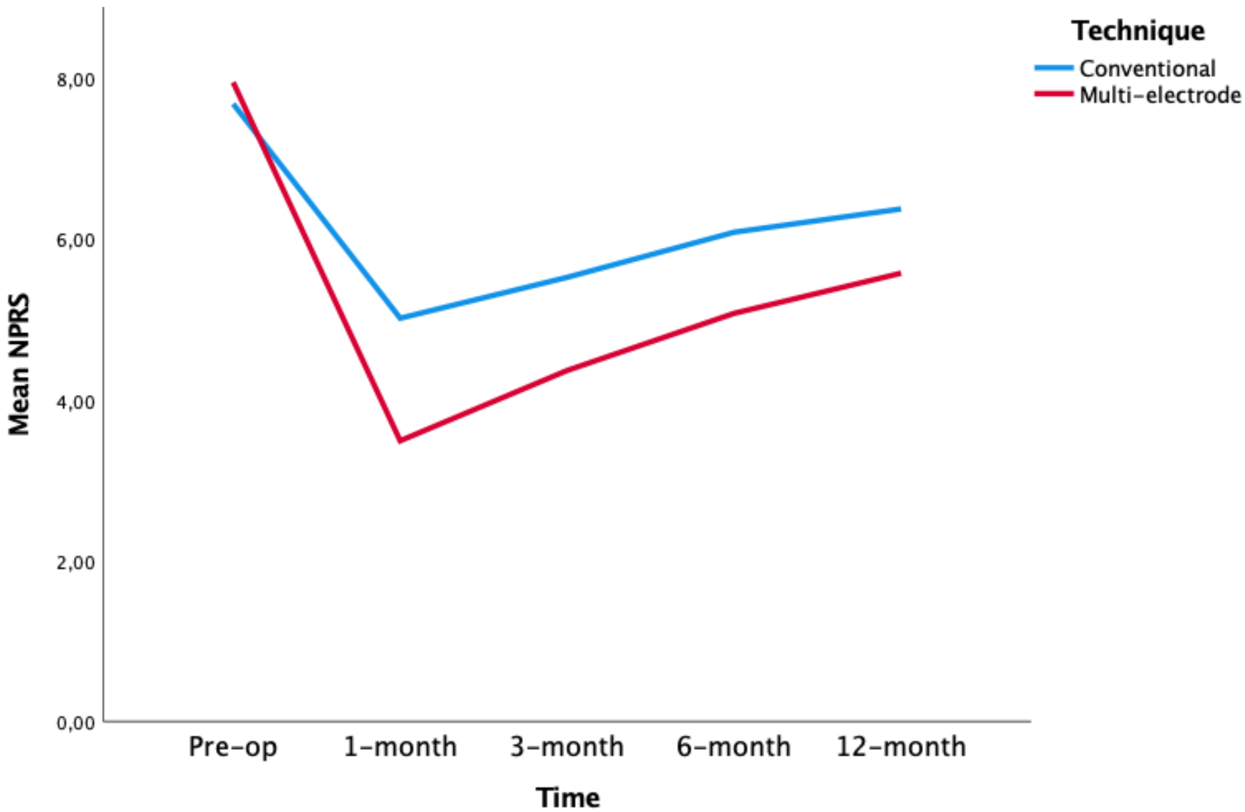


Figure 10. *Mean NPRS scores in both groups pre-intervention and after one, three, six and 12 months.*

In the conventional RF denervation group, 36.8% of the patients reported 50% or greater pain relief after one month, 26.3% after three months, 17.5% after six months, and 10.5% after 12 months. In comparison, these ratios were 71.9%, 53.1%, 40.6% and 29.7% in the multi-electrode sample group, respectively.

4.2.2. RMDQ

There was a significant difference between the mean RMDQ scores in the conventional RF group over time ($\chi^2_F(4)=78.1$, $p<0.001$, N= 57). However, after a significant decrease after one month (mean $RMDQ_{pre\text{-}RF}$= 15.4± 4.8, mean $RMDQ_{1\text{-}month}$=12.4± 5.8, z= 1.68, p< 0.001), the mean RMDQ score increased to 13.3 (±5.6) after three months, 13.9 (±5.5) after six months, and 14.5 (±5.5) after 12 months. The post-hoc analysis showed a significant difference between the mean RMDQ score pre-intervention and after six months (z=0.95, p=0.01), but not when comparing the score prior denervation and after one year (z=0.23, p= 1.0).

In the multi-electrode probe group, there was also a significant difference between the mean RMDQ scores over time ($\chi^2_F(4)=138.4$, $p<0.001$, N= 64). After one month, the mean RMDQ score decreased from 16.4 (±3.3) to 9.9 (±4.6) (z=2.45, p<0.001). The mean score increased after 3 months to 10.8 (±4.8), after six months to 12.1 (±4.5), and after twelve months to 13 (±4.2). In the post-hoc analysis there was a significant difference between the mean score prior to intervention and after 6 months (z=1.24, p<0.001), but not in comparison to the mean score after one year (z=0.57, p=0.41)

Comparing the results of both groups, the mean RMDQ score was significantly lower in the multi-electrode RF group after one month (U=1301.5, p=0.007), after three months (U=1264.5, p=0.004), after six months (U=1332, p=0.01), and after 12 months (1352.5, p=0.014), thus showing a significant benefit over conventional RF denervation (*Fig. 10).*

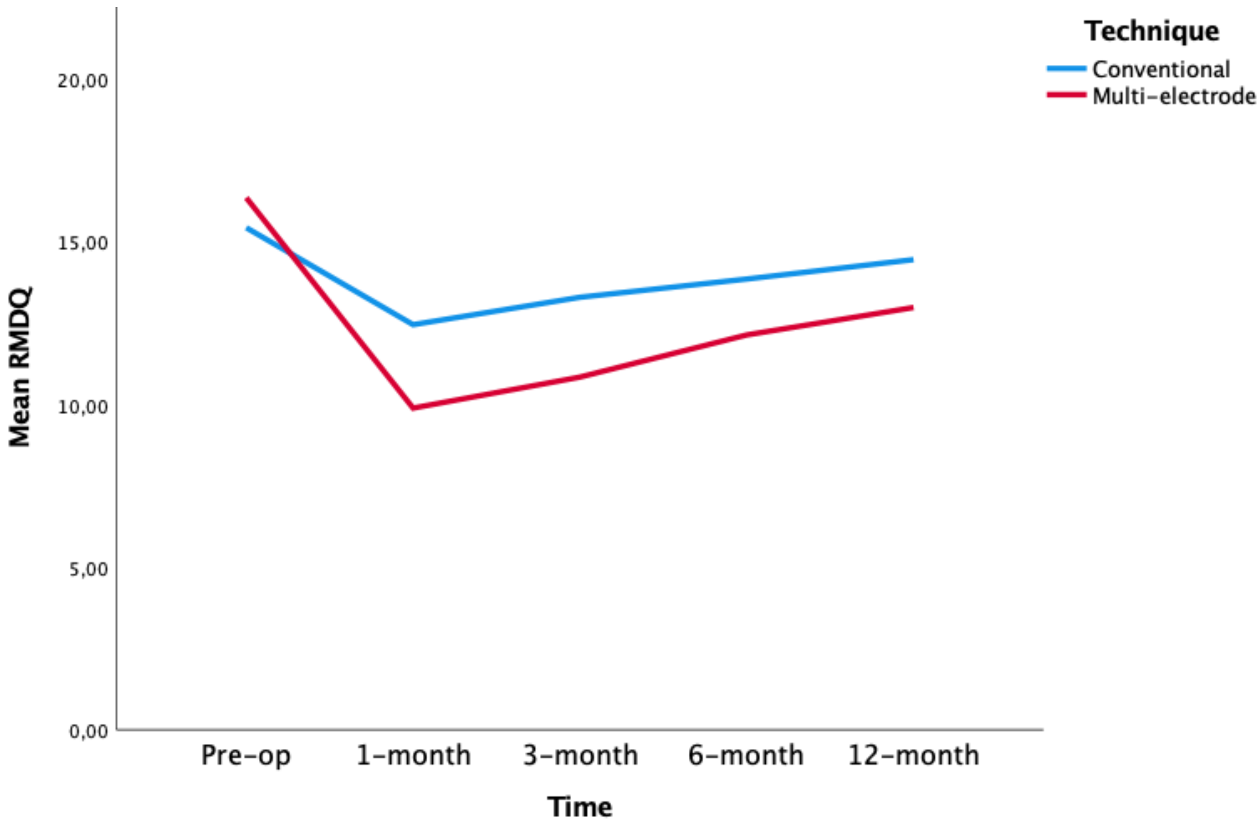


Figure 11. *Mean RMDQ scores in both groups pre-intervention and after one, three, six and 12 months.*

4.2.3. ODI

Patients in the conventional RF group reported significant differences in pain-related disability measured using the ODI over time ($\chi^2_F(4)=108.5$, p<0.001, N=57). The post-hoc analysis showed a significant decrease in the mean ODI score after one month (mean ODI_{pre-RF}= 25.8± 4.8, mean $ODI_{1-month}$= 20.1± 7.1, z= 2.04, p<0.001), followed by an increase after three months (21.2± 6.7), six months (22.6± 6.7), and 12 months (23.6± 6.3). The difference between the mean ODI score prior to denervation and after six months was significant (z=1.01, p=0.007), but there was no significant difference to the mean score after 12 months (z= 0.48, p=1.0).

There was also a significant difference between the mean ODI scores at different points of time in the multi-electrode RF group ($\chi^2_F(4)=169.1$, $p<0.001$, N=64). The mean ODI score was significantly lower after one month (16.3± 6) than prior to denervation (25.9± 5.2) (z=2.85, $p<0.001$). There was also a significant difference after three months (18.3± 5.3) (z=2.18, $p<0.001$) and after six months (19.9± 5.5) (z=1.26, $p<0.001$) in the post-hoc analysis. However, there was no significant difference between the mean score pre-intervention and after twelve months (21± 5.3) (z=0.58, p=0.39).

Patients treated with the multi-electrode probe had significantly lower ODI scores in comparison to the conventional RF denervation group at one month (U=1221.5, p=0.002), three months (U=1267, p=0.004), six months (U=1251.5, p=0.003), and twelve months (U=1268, p=0.004) after surgery (*Fig. 11*).

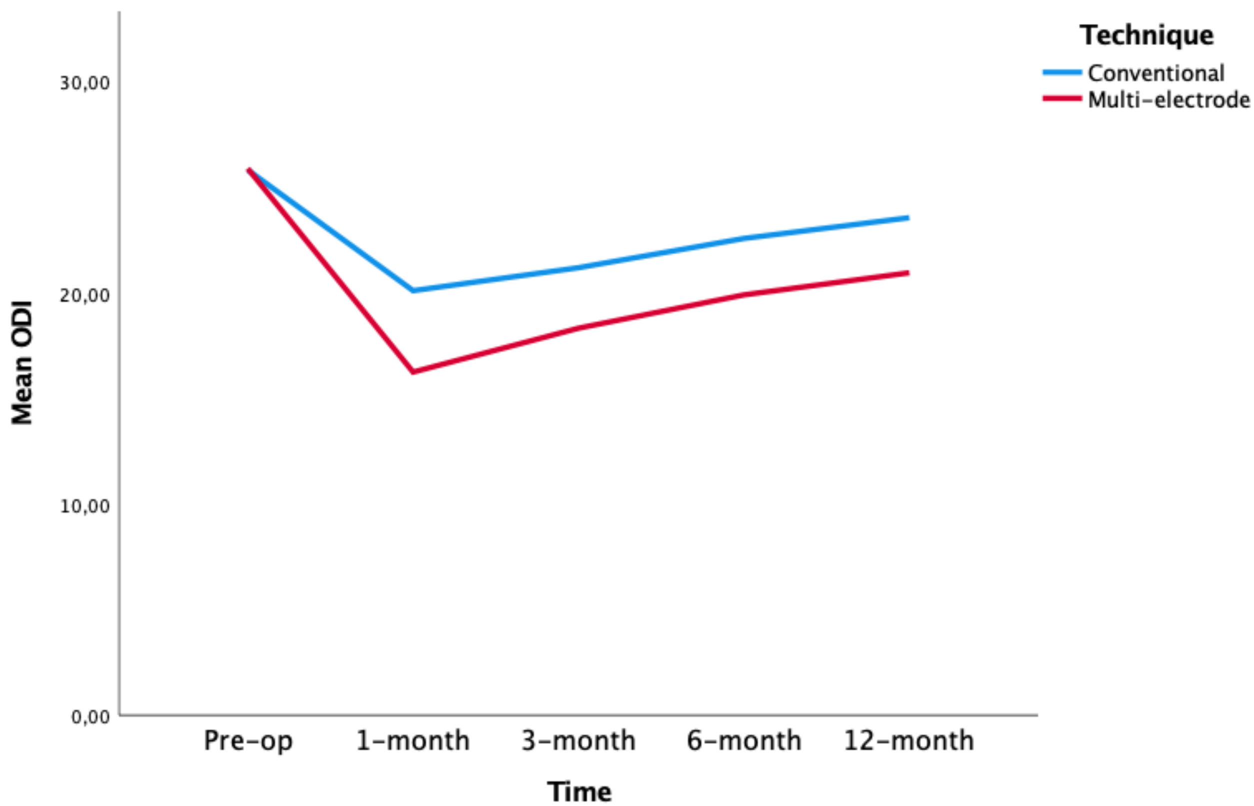


Figure 12. *Mean ODI scores in both groups pre-intervention and after one, three, six and 12 months.*

4.2.4. MOS SF-36

There was a significant difference in physical health related life quality measured with MOS SF-36 in the conventional RF group when comparing scores over time ($\chi^2_F(4)=77.3$, $p<0.001$, N=57). The post-hoc analysis showed a significant difference between the mean score prior to the intervention (27.9± 5.9), and after one month (34.5± 9.5) (z= -1.93, p<0.001) and three months (31.4± 8.5) (z= -1.18, p=0.01). However, the mean score after six months 29.6± 7.9) and after 12 months (29.3± 7.7) did not significantly differ from the mean score pre-intervention (pre-RF vs 6-months: z=-0.19, p=1.0, pre-RF vs 12-months: z=-0.02, p=1.0).

Differences between the mean physical health related MOS SF-36 scores measured at different times were also significant in the multi-electrode denervation group ($\chi^2_F(4)=98.0$, $p<0.001$, N=64). There was a significant difference between the mean score prior to intervention (28.6± 6.6) and after one month (39.2± 8.9) (z=-2.29, p<0.001), three months (37.6± 9.5) (z=-1.93, p<0.001), six months (36.1± 8.5) (z=-1.58, p<0.001), and 12 months (35.4± 8.5) (z=-1.35, p<0.001).

Physical health related MOS SF-36 scores were significantly higher in the multi-electrode probe group than in the conventional denervation group at one month (U=1304, p=0.007), three months (U=1178, p=0.001), six months (U=1044, p<0.001), and twelve months (U=1052, p<0.001) after intervention.

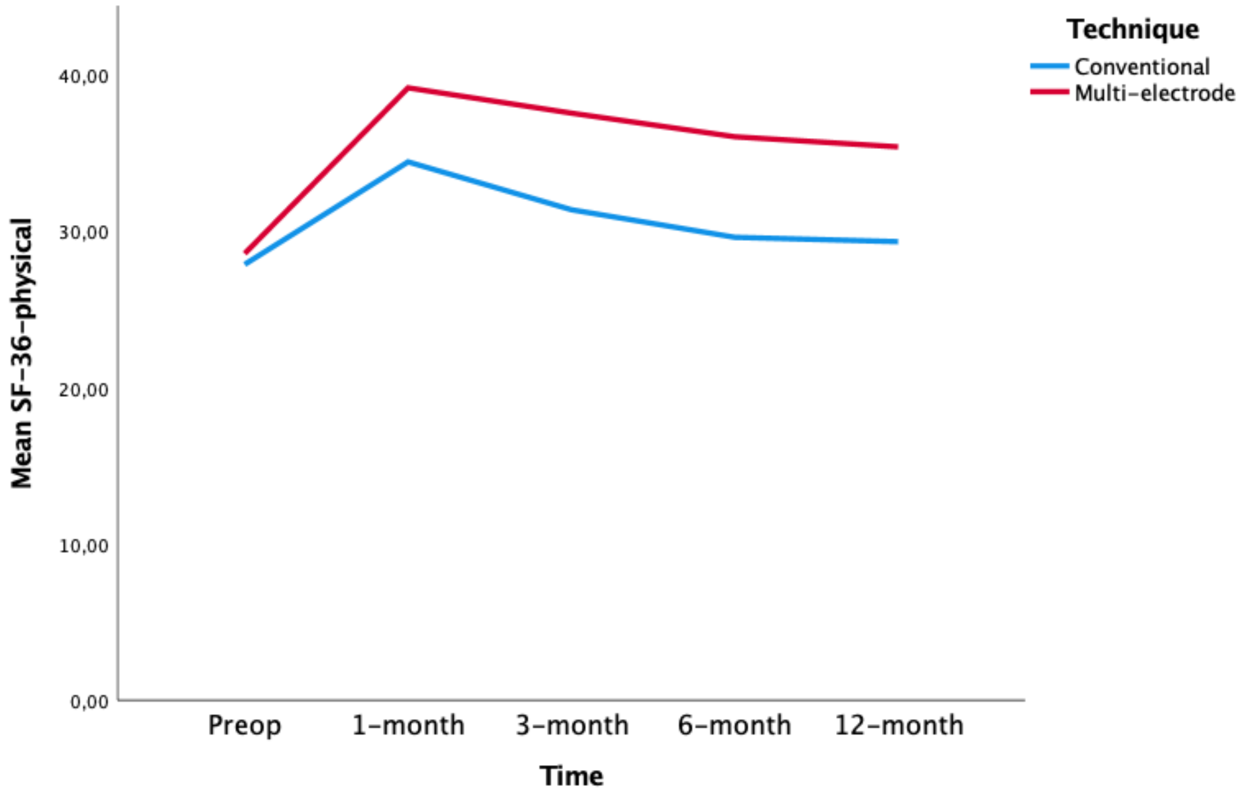


Figure 13. *Mean physical health related MOS SF-36 scores in both groups pre-intervention and after one, three, six and 12 months.*

4.3. Intraoperative parameters

The mean operation time was significantly lower in the multi-electrode denervation group (15± 4 min) in comparison to the conventional RF group (38± 16 min) ($p<0.001$).
During conventional RF denervation, patients had on average 104 s (±49) of fluoroscopic exposure time, whereas the mean exposure time in the multi-electrode probe group was only 18 s (± 49) ($p<0.001$).

5. Discussion

Low back pain is one of the most prevalent symptoms in adults and the second most common reason for sick leave (Hoy *et al.*, 2010), generating high socioeconomic costs in addition to the individual burden for each patient (Hagen *et al.*, 2000; Maniadakis and Gray, 2000; Walker, Muller and Grant, 2003; Wenig *et al.*, 2009). Back pain is associated with a number of conditions, and SIJ dysfunction is particularly frequent in young athletes and elderly patients (Cohen, Chen and Neufeld, 2013). RF denervation is a safe treatment option for patients with SIJ pain refractory to conservative therapy (Hansen *et al.*, 2007). In the last two decades, several denervation techniques were developed to enhance the efficacy.

5.1. Results of this study

In this study we compared two denervation techniques: traditional monopolar thermocoagulation and a novel technique using a multi-electrode probe. Both patient groups benefited from the therapy in terms of pain relief, pain-associated disability and quality of life. The accomplished effect gradually diminished in the course of the first year after the intervention. Denervation with the multi-electrode probe showed a significant advantage over the conventional monopolar denervation. Patients in this group had a better outcome directly after the intervention, and although chronic pain recurred in the following months, their pain score, pain-associated disability and quality of life were significantly improved in comparison to the pre-operative state, even after six months.

The high recurrence rate after six and 12 months in both groups is most likely caused by neural regeneration and deficient denervation. RF denervation equates to a third degree peripheral nerve injury according to Sunderland’s classification (Choi *et al.*, 2016). Recovery is slow, comprising approximately one inch per month, and not always complete, depending on the endoneurial injury (Flores, Lavernia and Owens, 2000).

5.2. Results in relation to current literature

Our results for the cohort treated with the multi-electrode probe are comparable with other studies using the same technique. In the study by Schmidt et al. (2014), 71.4% of the patients reported a pain relief greater than 50% after six weeks, compared to 71.9% in our study. After 6 months the percentage of these patients dropped to 50% in our study and to 53.1% in the study by Schmidt et al. Anjana Reddy et al. (2016) reported similar success rates after 6 months. Interestingly, Cheng et al (2016) had comparable results after creating a 60 mm long strip lesion using bipolar RF denervation with 7 needles placed lateral to the sacral foramina. Bellini and Barbieri (2016) reported considerably higher initial success rates also using a multi-electrode probe, with more than 90% of the patients experiencing over 50% pain relief after one month and 82% after three months. Despite reporting high recurrence rates after 6 and 12 months, the ODI scores continued to decline over the first year, which seems contradictory, as pain-associated disability should be coherent with pain intensity. Hegarty (2016) published a retrospective study with 12 patients where, contrary to our results and the results of other studies, pain intensity gradually declined over the observation period of 12 months. It is the only study with additional denervation of the L5 branch; however, based on the anatomical study by Roberts et al (2014), this is an unlikely explanation for the continuous improvement. This study showed that the L5 branch rarely contributes to the innervation of the posterior aspect of the SI, and when it does it usually unites with the S1 branch before reaching the PSNP. A more feasible explanation would be differences between the patient cohorts and post-operative care. Age over 65 years, longer history of SIJ pain and opioid use are all negatively associated with the clinical outcome after RF denervation (Cohen *et al.*, 2009). The average age in the patient cohort of Hegarty (2016) was lower than in our patient cohort, while Bellini and Barbieri (2016) did not disclose the age of their patients. Unfortunately, the duration of the symptoms and opioid use were not documented consistently for our patients and were also not published in the above-mentioned studies.

Our results for the cohort treated with conventional RF denervation were worse in comparison to the outcome reported by Cheng et al. (2012) or Cohen et al. (2009). While only 17.5% of our patients reported a pain relief of over 50% six months after the procedure, in the study by Cheng et al. (2012) this ratio was 40%, and in the study of Cohen et al. (2009) it was 47%. An important difference to the study of Cheng et al. (2012) is that in our cohort the ratio of patients with prior spinal surgery was significantly higher in comparison to the ratio in their subjects. Although prior spinal surgery was not predictive of clinical outcome after RF denervation in previous studies (Cohen *et al.*, 2009), it would be important to analyze the effect of previous spinal procedures, especially lumbar fusion, on the outcome of SIJ denervation with a larger patient cohort.

5.3. Considerations when choosing the ideal denervation technique

The anatomy and innervation of the SIJ is variable between individuals (Roberts *et al.*, 2014). For effective RF denervation, it is essential to cover all nerve fibers rising from the lateral branches of the posterior rami of the sacral spinal nerves. With the conventional monopolar technique, the surgeon targets the sacral lateral branches separately (Cohen, Chen and Neufeld, 2013; Roberts *et al.*, 2018). However the exit point out of the sacral foramen as well as the course and distribution of the individual branches varies (Roberts *et al.*, 2014). Using the multi-electrode probe, the aim is to denervate the lateral branches of S1-S3 with one large lesion placed lateral to the sacral foramina, close to the periosteum, instead of multiple smaller ones (Schmidt, Pino and Vorenkamp, 2014; Anjana Reddy *et al.*, 2016; Bellini and Barbieri, 2016; Gilligan *et al.*, 2016). Enlarging the lesion increases the probability of a thorough denervation of all lateral branches. Furthermore, using the multi-electrode denervation technique, only one probe needs to be placed correctly, while during conventional RF denervation there is a higher possibility for incomplete coverage of all nerval branches. Our study showed a superior pain relief using the multi-electrode probe, thus supporting this concept.

Another advantage of the multi-electrode probe is the reduced x-ray exposure and surgery time. With this method, only one electrode needs to be inserted, in comparison to three or more probes using the conventional ablation technique, and thus less control images are required. However, placing the multi-electrode probe correctly might be more challenging, especially in obese or large patients. Furthermore, the probe has a fixed curvature which is designed to match the sacral kyphosis, neglecting the high interindividual variability in the shape and size of the SIJ (Solonen, 1957; Dijkstra, Vleeming and Stoeckart, 1989). There is also a higher risk of skin injury caused by the most proximal contact if the probe is placed too superficially.

There are further aspects to consider when choosing the right denervation technique for a patient. As the periosteal positioning of the multi-electrode probe is very painful, all denervations in this technique were performed under general anesthesia, as an inpatient procedure, while the much less painful conventional RF ablations were performed under minimal or moderate sedation, as an ambulatory procedure. Although there were no anesthesia-related complications in either of the groups, general anesthesia is associated with higher risks, especially for patients with cardiac conditions (Finsterwald *et al.*, 2018), COPD (Hausman, Jewell and Engoren, 2015) or obesity (Bazurro, Ball and Pelosi, 2018). Additionally, an inpatient procedure with general anesthesia has much higher costs. However, in other studies, denervations with the multi-electrode probe were performed under moderate sedation (Gilligan *et al.*, 2016). In summary, the anesthetic method needs to be discussed with the patient and matched to their risk profile. Denervation with a multi-electrode probe can also be an option for multimorbid patients, with the hazard of higher discomfort during the procedure.

5.4. Limitations of the study

An obvious limitation of this study is its non-blinded, retrospective design. A randomized, prospective research would have been preferential. Blinding the patients when comparing two techniques with so many differences (single versus multiple entry points, different sedation methods) would have been very challenging. However, the physicians performing the follow-up appointments could have been blinded regarding the performed intervention. Furthermore, a placebo group could have been added with sham-denervation, as described by Cohen et al. (2008).

A further limitation is the difference in the sedation techniques between the two cohorts, which could also contribute to the clinical outcome.

An additional deficiency is the data lost because of inconsistent documentation, for example, data about changes in medication use or other additional conservative therapy. This would have been especially interesting, since opioids have been found to be significant outcome predictors (Cohen *et al.*, 2009). Nonetheless, because of the large number of subjects and very similar basic characteristics of our cohorts, we achieved significant differences in patient-reported outcome comparing these two techniques with a retrospective study design. Furthermore, socioeconomic and medico-economic factors were not considered in this study. Differences in the price of the probes, differing sedation methods and related perioperative care, as well as lower socioeconomic costs through successful treatment, should be considered.

5.5. Summary

Denervation with a multi-electrode probe is a safe and efficient way to treat SIJ pain. In our study, denervation with the multi-electrode probe showed a significant advantage over conventional RF ablation regarding the clinical outcome, x-ray exposure time and length of surgery. Both denervation groups had a high relapse rate after six and 12 months. Because of differences in the sedation methods, procedures with the multi-electrode probe had higher additional costs. However, it is also possible to perform ablation in this technique in conscious sedation. Considering the differences between individual studies, our results are in line with the outcome of subjects in other research (Cohen *et al.*, 2009; Cheng *et al.*, 2012; Schmidt, Pino and Vorenkamp, 2014; Anjana Reddy *et al.*, 2016; Bellini and Barbieri, 2016; Hegarty, 2016). A prospective, randomized, placebo-controlled trial could further support our results. It would be also beneficial to compare this new technique with other denervation procedures, such as cooled RF denervation or bipolar denervation.

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Eidesstattliche Versicherung

„Ich, Petra Heiden, versichere an Eides statt durch meine eigenhändige Unterschrift, dass ich die vorgelegte Dissertation mit dem Thema: Comparison of two techniques for denervation of the sacroiliac joint/ Der Vergleich von zwei Methoden zur Denervation des Iliosakralgelenkes selbstständig und ohne nicht offengelegte Hilfe Dritter verfasst und keine anderen als die angegebenen Quellen und Hilfsmittel genutzt habe.

Alle Stellen, die wörtlich oder dem Sinne nach auf Publikationen oder Vorträgen anderer Autoren/innen beruhen, sind als solche in korrekter Zitierung kenntlich gemacht. Die Abschnitte zu Methodik (insbesondere praktische Arbeiten, Laborbestimmungen, statistische Aufarbeitung) und Resultaten (insbesondere Abbildungen, Graphiken und Tabellen) werden von mir verantwortet.

Ich versichere ferner, dass ich die in Zusammenarbeit mit anderen Personen generierten Daten, Datenauswertungen und Schlussfolgerungen korrekt gekennzeichnet und meinen eigenen Beitrag sowie die Beiträge anderer Personen korrekt kenntlich gemacht habe (siehe Anteilserklärung). Texte oder Textteile, die gemeinsam mit anderen erstellt oder verwendet wurden, habe ich korrekt kenntlich gemacht.

Meine Anteile an etwaigen Publikationen zu dieser Dissertation entsprechen denen, die in der untenstehenden gemeinsamen Erklärung mit dem/der Erstbetreuer/in, angegeben sind. Für sämtliche im Rahmen der Dissertation entstandenen Publikationen wurden die Richtlinien des ICMJE (International Committee of Medical Journal Editors; www.icmje.org) zur Autorenschaft eingehalten. Ich erkläre ferner, dass ich mich zur Einhaltung der Satzung der Charité – Universitätsmedizin Berlin zur Sicherung Guter Wissenschaftlicher Praxis verpflichte.

Weiterhin versichere ich, dass ich diese Dissertation weder in gleicher noch in ähnlicher Form bereits an einer anderen Fakultät eingereicht habe.

Die Bedeutung dieser eidesstattlichen Versicherung und die strafrechtlichen Folgen einer unwahren eidesstattlichen Versicherung (§§156, 161 des Strafgesetzbuches) sind mir bekannt und bewusst.“

Datum Unterschrift

Anteilserklärung an etwaigen erfolgten Publikationen

Petra Heiden hatte folgenden Anteil an den folgenden Publikationen:

Bayerl SH, Finger T, Heiden P, Esfahani-Bayerl N, Topar C, Prinz V, Woitzik J, Dengler J, Vajkoczy P. Radiofrequency denervation for treatment of sacroiliac joint pain – comparison of two different ablation techniques. Neurosurg Rev 2020;43:101-107.

Substantielle Mitwirkung an der Entwicklung des Studiendesings

Zusammentragen von Patientendaten

Aufarbeitung und Auswertung der klinischen Ergebnisse

Substantielle Mitwirkung an Entwurf und Fertigung der Publikation in der vorliegenden Form

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Unterschrift des Doktoranden/der Doktorandin

Curriculum vitae

Mein Lebenslauf wird aus datenschutzrechtlichen Gründen in der elektronischen Version meiner Arbeit nicht veröffentlicht

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