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Radiostereometric analysis of sacroiliac joint movement and outcomes of pelvic joint fusion

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List of Papers

This PhD dissertation is based on the following papers:

1. Kibsgård T J, Røise O, Stuge B, Röhrl S M. Precision and accuracy measurement of radiostereometric analysis applied to movement of the sacroiliac joint. Clin Orthop Relat Res 2012; 470(11): 3187-94.

2. Kibsgård T J, Røise O, Sturesson B, Röhrl S M, Stuge B. Radiosteriometric analysis of movement in the sacroiliac joint during a single-leg stance in patients with long-lasting pelvic girdle pain. Clin Biomech (Bristol, Avon) 2014; 29(4): 406-11.

3. Kibsgård T J, Røise O, Stuge B. Pelvic joint fusion in patients with severe pelvic girdle pain – a prospective single-subject design study. BMC Musculoskelet Disord 2014; 15(1): 85.

4. Kibsgård T J, Røise O, Sudmann E, Stuge B. Pelvic joint fusions in patients with chronic pelvic girdle pain: a 23-year follow-up. Eur Spine J 2013; 22(4): 871-7.

Abbreviations

| Abbreviation | Definition                        |
|--------------|-----------------------------------|
| CI           | Confidence Interval               |
| CT           | Computer Tomography               |
| MRI          | Magnetic Resonance Imaging        |
| RSA          | Roentgen Stereophotogrammetric Analysis |
| VAS          | Visual Analogue Scale             |
| ODI          | Oswestry Disability Index         |
| SF-36        | Short Form-36                     |
| SIJ          | Sacroiliac Joint                  |
| ME           | Mean Error of Rigid Body Fitting  |
| CN           | Condition Number                  |
| MIS          | Minimal Error of Rigid Body Fitting |
| LBP          | Low Back Pain                     |
| PGP          | Pelvic Girdle Pain                |
| BMI          | Body Mass Index                   |
| A-P          | Anterior - Posterior              |
| ASLR         | Active Straight Leg Raise         |
| LOS          | Limit of significans              |

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Thesis at a glance

Paper I

**Background** – Different techniques have been used to quantify the movement of SIJ’s. These include RSA, but the accuracy and precision of this method have not been properly evaluated and it is unclear how many markers are required and where they should be placed to achieve proper accuracy and precision. The purpose of this study was to test accuracy and precision of RSA, applied to the SIJ, in a phantom model and in patients.

**Methods** – We used a plastic phantom attached to a micrometer to obtain a true value of the movement of the SIJ and compared this value with the measured value obtained by RSA; the difference represented the accuracy. The precision of the system was measured by double examination in the phantom and in six patients, and was expressed by a limit of significance (LOS). We analyzed different marker distributions to find optimal marker placement and number of markers needed.

**Results** – The accuracy was high and we identified no systematic errors. The precision of the phantom was high with a LOS less than 0.25° and 0.16 mm for all directions, and in patients, the precision was less than 0.71° for rotations and 0.47 mm translations. No markers were needed in the pubic symphysis to obtain good precision.

**Conclusions** – The accuracy and precision are high when RSA is used to measure movement in the SI joint and support the use of RSA in research of SIJ motion.

Paper II

**Background** – Chamberlain’s projections (anterior-posterior x-ray of the pubic symphysis) have been used to diagnose SIJ mobility during the single-leg stance test. This study examined the movement in the SIJ during the single-leg stance test with precise RSA.

**Methods** – Under general anesthesia, tantalum markers were inserted into the dorsal sacrum and the ilium of 11 patients with long-lasting and severe pelvic girdle pain. After two to three weeks, a RSA was conducted while the subjects performed a single-leg-stance.

**Results** – Small movements were detected in the SIJ during the single-leg stance. In both the standing- and hanging-leg sacroiliac join, a total of 0.5° rotation was observed; however, no translations were detected. There were no differences in total movement between the standing- and hanging-leg SIJ.

**Interpretation** – The movement in the SIJ during the single-leg stance is small and almost undetectable by the precise RSA. A complex movement pattern was seen during the test, with a combination of movements in the two joints. The interpretation of the results of this study is that, the Chamberlain examination likely is inadequate in the examination of SIJ movement in patients with PGP.

Paper III

**Background** – The fusion of the pelvic joints in patients with severe PGP is a controversial and insufficiently studied subject. The aims of this study were to evaluate physical function and pain after SIJ fusion.

**Methods** – A single-subject research design study with repeated measurements was conducted; pre-operatively and 3, 6, and 12 months post-operatively. The outcome measures considered were the Oswestry disability index (ODI), visual analogue scale (VAS), and SF-36. Eight patients with severe PGP received open-accessed unilateral anterior SIJ fusion and concomitant fusion of the pubic symphysis.

**Results** – Seven patients reported positive results from the surgery. At 1 year post-operation, significant (p < 0.001) reductions in ODI (54 to 37) and VAS (82 to 57) were reported. The physical functioning, bodily pain, and social functioning scores in the SF-36 were also improved.

**Conclusion** – Positive and significant changes in disability and pain at 1 year after SIJ fusion were observed. Despite these positive results, open accessed anterior fusion of the SIJ was associated with adverse events and complications such as infection and nerve damages.

Paper IV

**Purpose** – Fusion of the SIJ has been a treatment option for patients with severe PGP. The primary aims were to evaluate the long-term outcomes in patients who underwent SIJ fusion and to compare 1-year outcomes with long-term outcomes. The secondary aim was to compare patients who underwent SIJ fusion with a comparable group who did not.

**Methods** – This study includes 50 patients that underwent SIJ fusion between 1977 and 1998. Function (ODI), pain intensity (VAS) and health-related quality of life (SF-36) were determined according to a patient-reported questionnaire. The questionnaire scores were compared with previously recorded 1-year outcomes and with questionnaire scores from a group of 28 patients who did not undergo SIJ fusion.
Results – The patients who underwent SIJ fusion reported a mean ODI of 33 (95% CI 24–42) and a mean VAS score of 54 (95% CI 46–63) 23 years (range 19–34) after surgery. Regarding quality of life, the patients reported reduced physical function, but mental health was not affected in the same manner. The patients with successful 1-year outcomes (48%) retained significantly improved function and reduced pain levels compared with the subgroup of patients with unsuccessful 1-year outcomes (28%). The patients who underwent surgery did not differ from the non-surgery group in any outcome at the long term follow-up.

Conclusions – Patients treated with SIJ fusion had moderate disability and pain 23 years after surgery, and the 1-year outcomes were sustained 23 years after surgery. Although many fused patients reported good outcome, this group did not differ from the comparable non-surgical group.
Introduction

Pelvic girdle pain

The sacroiliac joint (SIJ) can be a source of pain for 13-30% of patients with low back pain (LBP) (Vleeming et al. 2008) and for possibly an even greater proportion of patients suffering from “failed back surgery” (DePalma et al. 2011, Katz et al. 2003). This pain may be caused by a specific pathology of the joint (Bellamy et al. 1983), but the specific role of the SIJ in unspecific pelvic girdle pain (PGP) disorder remains unknown. PGP is a common complaint in pregnancy that can cause disability, and in some women, the complaint continues after delivery (Albert et al. 2002, Vleeming et al. 2008). The origin and diagnosis of PGP are also unclear because radiological findings are often absent, and the diagnostic criteria lack sufficient evidence. It has, however, become increasingly clear that the clinical presentation and disability level in patients with PGP differ from those in patients suffering from LBP (O’Sullivan and Beales 2007, Robinson et al. 2010).

Terminology

Many different terms have been used to describe pelvic pain (Wu et al. 2004), and some of these terms describe possible etiologies, such as “relaxation”, “instability” and “arthropathy”. Because the origin of pain in PGP is uncertain, these terms might be incorrect or misleading. To obtain a single term, the authors of the European guidelines for the diagnosis and treatment of pelvic girdle pain proposed the term PGP, together with the following definition (Vleeming et al. 2008).

“Pelvic girdle pain generally arises in relation to pregnancy, trauma, arthritis and osteoarthritis. Pain is experienced between the posterior iliac crest and the gluteal fold, particularly in the vicinity of the SIJ. The pain may radiate in the posterior thigh and can also occur in conjunction with/ or separately in the symphysis. The endurance capacity for standing, walking, and sitting is diminished. The diagnosis of PGP can be reached after exclusion of lumbar causes. The pain or functional disturbances in relation to PGP must be reproducible by specific clinical tests.”

This definition has been proposed for pelvic musculoskeletal pain to exclude gynecological and/or urological disorders and to promote consistent use of terminology.

Epidemiology

PGP is most commonly reported in pregnancy, but some patients also develop PGP after minor trauma or without any specific reason. The prevalence of PGP during pregnancy has been estimated to be approximately 20% (Vleeming et al. 2008), and approximately 50% of patients report LBP during pregnancy (Berg et al. 1988, Wu et al. 2004, Robinson et al. 2006, Ostgaard et al. 1991). Most women recover, but approximately 10-25% of women continue to have complaints after delivery (Albert et al. 2001, Wu et al. 2004, Larsen et al. 1999, Vleeming et al. 2008, Bjelland et al. 2013b), and approximately 5% suffer from pain that is sufficiently severe to require medical assistance (Wu et al. 2004). Furthermore, it seems that patients with symptoms in all three pelvic joints during pregnancy have an increased risk of suffering from disabling PGP 2 years after delivery compared to patients with pain in one or two joints (Albert et al. 2001). PGP occurs frequently during pregnancy and has a good prognosis of rapid regression of symptoms, but in some cases, the pain becomes long-lasting and debilitating.

The SIJ has also been suggested to be a possible source of pain in non-pregnant patients, such as patients with non-specific LBP. The prevalence reported has varied greatly and has been estimated to be somewhere between 10% and 62% (Simopoulos et al. 2012). Without a gold standard to diagnose the SIJ pain, the prevalence has been difficult to establish. Intra-articular SIJ injections have been used as a gold standard to estimate the prevalence of SIJ pain in patients with LBP. The effects of these injections have been reported to be positive or negative, however, with different cut-off values defining a positive test result. Some investigators used a single injection as the cut-off, whereas others did not define the test as positive if the test was not replicated with a control block (Simopoulos et al. 2012). The selection of patients is another factor that has had a large influence on prevalence. The lowest prevalence has been observed in unselected groups of patients with unspecific LBP, and in studies including patients with a probability of SIJ pain, the prevalence has increased. Although the prevalence varies, it is highly possible that the SIJ is a source of pain in patients with non-specific LBP, but without a gold standard, these numbers are uncertain.

Etiology

The etiology of PGP is poorly understood, but there is agreement that the cause is multi-factorial, and it must be viewed in a bio-psycho-social framework (O’Sullivan and Beales 2007). Many attempts have been undertaken to understand the origin of PGP, and the factors that are believed to be of importance include hormonal, genetic, psychological, neuropathological, biomechanical, pathoanatomical and social factors (O’Sullivan and Beales 2007, Kanakaris et al. 2011).

All of these different factors can contribute to PGP, but the extent to which each factor contributes is likely different in
each patient. The hormonal influence of relaxin and progesterone on the ligaments, with smoothing and relaxing effects, has been well established (Albert et al. 1997), but the association between hormone levels and PGP has been debated (Albert et al. 1997, Vollestad et al. 2012, Bjelland et al. 2013a). The sacropelvic ligaments have been of interest because many patients with PGP report tenderness in these ligaments (Torstensson et al. 2009, Palsson and Graven-Nielsen 2012). The relaxing effects of hormones on the ligaments during pregnancy have contributed to the biomechanical understanding or misunderstanding of pelvic relaxation and instability. Separation of the pubic symphysis has been used as an objective measurement of pelvic joint movement, and pubic movement has been reported to be greater in patients with PGP than in controls (Mens et al. 2009). However, the variations in the movements and the overlap in range between patients with and without PGP are too large to use these measurements as diagnostic tools. Although increased movement can be observed during and shortly after pregnancy, there has been no documentation of a correlation between sacroiliac mobility and symptoms in patients with long-term PGP (Sturesson et al. 1989, Vleeming et al. 2012). However, a correlation has been found between asymmetrical laxity of the SIJ and the intensity of symptoms (Damen et al. 2001). Because pelvic relaxation during pregnancy is a normal physiological response, and the majority of pregnant women do not experience pain, the importance of this minimal increase in pelvic joint movement is uncertain. Although many factors have been proposed to be important when PGP develops and persists, it has been suggested that pain caused by dysfunction in the SIJ is a plausible explanation (Ostgaard et al. 1991). Altered muscle activation has been observed in patients with PGP (Mens et al. 2009, O’Sullivan and Beales 2007, Wu et al. 2008, Beales et al. 2009, Stuge et al. 2012, Stuge et al. 2013). Optimal muscular control is important for stabilizing the SIJ as well as the entire pelvic girdle (Snijders et al. 1993), and a treatment program, including training in motor control, has been shown to reduce PGP (Stuge et al. 2004a, O’Sullivan and Beales 2007, Stuge et al. 2004b). When researching PGP, the bio-psycho-social model should be applied because psychological and social factors also seem to contribute when a patient develops chronic pain syndrome. Psychological factors, such as emotional distress and catastrophizing during pregnancy, have been shown to increase the risk of PGP (Beales et al. 2009, Bjelland et al. 2013b, Olsson et al. 2012), and social factors, such as physically demanding work and inconvenient work hours, have also been found to increase the risk of PGP (Juhl et al. 2005). These findings are in contrast to the strict reductionist biological model of medicine, in which the disease can be explained by an underlying pathological process or a developmental abnormality.

**Diagnostics**

**Medical history**

The clinical presentation of patients with PGP varies, but there are certain common characteristics. Often, the pain is located over the SIJ region and extends below the posterior spine, along the long dorsal ligament (Figure 4), deep into the gluteal region and into the pubic symphysis. The pain worsens with standing, sitting and walking (Vleeming et al. 2008, Wu et al. 2004), and many patients report “catching” of the leg (Sturesson et al. 1997). Although many patients have reported these clinical symptoms, the medical history alone has been reported to have limited value compared to an SIJ injection as the gold standard (Dreyfuss et al. 1996).

**Clinical tests**

There have been many reports with very different results regarding the reliability and validity of clinical tests in the diagnosis of PGP. The main reason for this variation has been the lack of a gold standard with which to compare the tests (Vleeming et al. 2008). Dreyfuss et al. (1996) did not find any reasonable value of medical history or clinical testing compared to diagnostic SIJ block, but other researchers have found adequate sensitivity and specificity with clinical testing, particularly if multiple tests were used (Laslett et al. 2005a). In two systematic reviews (van der Wurff et al. 2000b, van der Wurff et al. 2000a), the authors reported both the reliability and validity of clinical tests to be poor; however, later studies of higher quality reported more promising results (Laslett et al. 2006). These tests can be divided into provocation tests and functional tests (Vleeming et al. 2008).

Provocation tests aim to stress the SIJ and the surrounding ligaments and to trigger actual pain. Laslett (2005) emphasized that the test should be regarded as positive if it reproduces familiar pain. The use of multiple tests strengthens the probability of the diagnosis (Laslett et al. 2003, Laslett et al. 2005b, Slipman et al. 1998, Stanford and Burnham 2010, van der Wurff 2006, van der Wurff et al. 2006, Vleeming et al. 2008). The above-mentioned studies used 3 of 5-6 positive provocation tests as a cut-off and SIJ injection as the gold standard. The studies reported sensitivity of 82-94% and specificity ranging from 57% to 78%. As shown in Table 1, if only 1 positive test was chosen, the sensitivity was high because a patient with PGP most likely tested positive on one test. Because these tests loaded the SIJ in different ways, the patients most likely did not respond to all tests; consequently, the sensitivity decreased, together with an increased cut-off for positive clinical tests (Table 1). The specificity was low if only 1 test of 5 was positive, but if 5 of 5 tests were positive, the specificity was 88–100%.

To provoke the pubic symphysis pain, two tests have been used: the modified Trendelenburg test and palpation of the pubic symphysis (Albert et al. 2000, Vleeming et al. 2008). The modified Trendelenburg test is considered positive if
the patient experiences pain in the symphysis when standing on one leg with the other hip in 90° of flexion (Albert et al. 2000). The sensitivity has been reported to be 40–62% and the specificity to be 99% (Vleeming et al. 2008). Gentle palpation of the symphysis, with pain 5 seconds after removal of the hand, has been shown to have sensitivity of 60–81% and specificity of 85–99% and to have good inter-examiner agreement (kappa = 0.89) (Albert et al. 2000, Kristiansson and Svardsudd 1996).

The most widely used functional test is the active straight leg raise (ASLR) (Figure 1) (Mens et al. 1999). When Mens et al. (1999) applied this test in 200 patients with suspected PGP and compared these patients to 50 healthy controls, they found, when a cut-off score between 0 and 1 was chosen, sensitivity of 0.87 and specificity of 0.94. The same test proved to be well-correlated with the severity of symptoms (Mens et al. 2002).

### Radiological examinations

Computer tomography is the best examination for visualizing the bony anatomy of the SIJ, but one challenge is that radiological findings of degeneration can be observed in normal subjects as well as in patients with SIJ pain. In a study of 45 asymptomatic subjects, Vogler et al. (1984) reported symmetrical and normal CT scans in subjects younger than 30 years old, but with increasing age, the radiological findings changed. The joint space became less uniform, and subchondral sclerosis was observed. In the oldest participants (older than 59 years old), the investigators discovered high percentages of osteophytes, cysts, erosions and ankylosis. These findings were verified by Shibata et al. (2002), who reported joint space narrowing (87%), sclerosis (52%) and osteophytes (68%) in 190 patients who were asymptomatic for SIJ, with a higher prevalence with increasing age. Subsequently, Elgafy et al. (2001) compared degenerative CT findings with SIJ injections to examine the relationship between radiological findings and symptoms. Of 62 patients with positive SIJ injections, 42.5% had normal CT findings, and when these cases were compared to a control group of asymptomatic patients, the authors found sensitivity of 58% and specificity of 69% for CT. In summary, these CT findings could be found in patients with PGP and suspected SIJ pain, as well as in asymptomatic subjects, which limited the diagnostic value of CT scans for the diagnosis of PGP (Vogler, III et al. 1984, Elgafy et al. 2001, Shibata et al. 2002).

Magnetic resonance imaging has been reported to play an important role in diagnosing inflammatory SIJ pathology and particularly in diagnosing early changes in SIJ spondyloarthropathies (Puhakka et al. 2004a, Puhakka et al. 2004b, Vleeming et al. 2008). The use of MRI can be used to identify these changes, but it has primarily been used to exclude serious pathology.

Radionuclide bone scanning has also been used to diagnose SIJ pathology, but when scintigraphy is compared to SIJ injections, the sensitivity of the former has proven to be low. When scans were considered either positive or negative, Slipman et al. (1996) reported sensitivity of 13%, indicating that 87% of the patients with positive SIJ injections had negative bone scans. Subsequently, Maigne et al. (1998) used quantita-

### Table 1. Sensitivity and specificity of combinations of tests

| Author     | Tests                  | Reduction in VAS | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
|------------|------------------------|------------------|---|---|---|---|---|---|---|
| Van der Wurff (2006) | 1, 2, 3, 4, 5 | > 50%            | 100 | 0 | 100 | 42 | 93 | 58 | 85 | 78 |
| Laslett (2003)   | 1, 2, 3, 5, 6 | > 80%            | 91  | 78 |     |     |     |     |     |     |
| Laslett (2005)   | 1, 2, 3, 5, 6 | > 80%            | 100 | 44 | 93 | 66 | 94 | 78 | 60 | 81 | 27 | 88 |
| Stanford (2010)  | 2, 3, 4, 6, 7 | > 80%            | 82  | 57 |     |     |     |     |     |     |

Se = sensitivity, and Sp = specificity of clinical tests. Tests used: 1 – Distraction, 2 – Compression, 3 – Thigh trust, 4 – Patrick sign, 5 – Gaenslen, 6 – Sacral thrust, 7 – Bilateral Gaenslen
tive radionuclide bone scans and found higher uptake in joints with positive SIJ injections, and they reported sensitivity of 46% and specificity of 89%. The radionuclide bone scan is therefore an inadequate tool for screening the SIJ as the origin of pain (Slipman et al. 1996, Maigne et al. 1998).

The sacroiliac joint

The SIJ has been considered one of many etiologies of PGP and LBP. Before herniated discs were discovered to be a cause of LBP, the SIJ was believed to play a central role as a pain generator. Subsequently, however, focus moved away from the SIJ toward the herniated disc. More recent injection studies have discovered that a significant proportion of LBP patients have SIJ pain (Schwarzer et al. 1995, Simopoulos et al. 2012), and the SIJ has also been suggested to be a significant contributor to failed back surgery (Katz et al. 2003, Maigne and Planchnon 2005). Hence, the SIJ might play a role in the development of PGP, as well as having a potentially important role in patients with LBP.

The sacroiliac joint in historical perspective

There has been great interest in the SIJ in the medical literature, and according to several authors (Buchowski et al. 2005, Weisl 1955, Lynch 1920, Vleeming et al. 2012), the SIJ was first described by Hippocrates as a source of pain. Hippocrates (Figure 2) described the “disjunctio pelvica” as a reason for pain during pregnancy, but it was originally believed that the SIJ only became mobile during pregnancy. Since the time of Hippocrates, debate has persisted regarding the degree of mobility of the SIJ. According to Weisl (1955), Dimerbroeck stated in 1689 that the SIJ was likely also mobile also in men and in women apart from pregnancy, and this fact was later confirmed by multiple cadaver studies (Weisl 1955). From these cadaver studies, evidence emerged that the SIJ is a synovial joint and therefore must move. Subsequent measurements of the true conjugate distance showed differences between different postures, indicating movement of the sacrum relative to the innominate bone (von Schubert 1929, Weisl 1955). Later authors concluded that the movement of the SIJ was mostly rotational around an axis perpendicular to the joint surface.

In 1930, Chamberlain described an radiographic method for indirectly measuring SIJ movement. Because SIJ movements were assumed to be mostly rotational, the movement measured in the pubic symphysis was interpreted as an indirect measurement of SIJ movement (Chamberlain 1930). Chamberlain also found that the movement observed in the pubic symphysis, and indirectly in the SIJ, could be correlated with pain. This relationship between Chamberlain’s radiographic studies and pain was also reported by other researchers, but the findings were not consistent (Anderson and Peterson 1944, Mens et al. 1999). During this time period, the SIJ was a well-established cause of ischialgia and LBP, but it lost attention when Mixter and Barr (Mixter and Barr 1934) first described a ruptured intervertebral disc as a source of ischialgia. Despite Anderson’s (1944) statement, “There seems to be no question at the present time that the SIJ is a movable joint,” and the convincing results of Weisl (1955) showing SIJ movement, interest in the SIJ declined. Subsequently, Solonen (1957) stated that because of the strong ligaments and irregular shape of the SIJ, the joint is immobile, and this observation was more or less considered to be true for a long period of time. In the 1980s, interest in the SIJ returned, and there were several studies during this period that attempted to establish and understand the biomechanical properties of the SIJ (Weisl 1955, Solonen 1957, Smidt et al. 1995, Smidt et al. 1997, Sturesson 1999, Sturesson et al. 1989, Sturesson et al. 1999, Sturesson et al. 2000a, Sturesson et al. 2000b).

Anatomy

The SIJ is a diarthrodial joint, but it is unique because the sacral surface has hyaline cartilage, and the ilial surface has fibrocartilage (Foley and Buschbacher 2006, Forst et al. 2006, Vleeming et al. 2012). The joint’s anatomy is variable between subjects with regard to its size and shape, and the joint changes over one’s lifetime (Vleeming et al. 1990, Vogler, III et al. 1984). The joint is L-shaped and is formed from the sacral bodies from S1 to S3. The joint line is smooth in childhood but becomes more irregular in adulthood, which minimizes movement (Vleeming et al. 2012). In addition to the irregular joint surface, primary stabilization of the joint is accomplished by different strong ligaments (Figures 3 and 4). The anterior ligament is more or less a thickening of the anterior capsule, and it is not as strong as the dorsal ligaments. The dorsal ligaments consist of different defined ligaments, of which the intersosseous ligament is the strongest. This ligament is multidirectional and is an important stabilizer, allowing great forces to be transferred from the spine to the lower extremities. The other ligaments that stabilize this joint include the long and short dorsal sacroiliac ligament, the sacrotuberous ligament and the iliolumbar ligament (Figures 3 and 4). The bony anatomy and these ligaments ensure that the pelvic girdle is not a rigid ring but instead works as a suspension mechanism that allows forces to be transferred without causing a fracture to the pelvis (Vleeming et al. 2012).
No muscles directly cross the SIJ, but the interactions of adjacent muscles and fascial structures are dynamic stabilizers of the SIJ. The biceps femoris, the gluteus maximus and the piriformis are connected to the ligaments around the SIJ and contribute to the functional stability of the joint (Snijders et al. 1993). Additionally, the pelvic floor muscles have been reported to add stiffness to the pelvic ring (Snijders et al. 1993, Pool-Goudzwaard et al. 2004). Furthermore, the deep abdominal muscles connecting to the thoracolumbar fascia are believed to contribute to the stability of the SIJ (vleeming et al. 1995).

**Stability of the SIJ**

A biomechanical model has been created to describe the forces that contribute to the stability of the SIJ. Snijders et al. (1993) described a model based on the theory of form and force closure. Form closure refers to a situation in which the joint is stable, without any need for additional stabilizing forces, and force closure is a situation in which the joint is stabilized by friction and compression forces. The SIJ is believed to be stabilized by a combination of form closure (ridges and grooves in the SIJ) and force closure (ligaments and muscles) (Snijders et al. 1993, Vleeming et al. 1990) (Figure 5).

The range of motion in the SIJ is small, both in patients with PGP and in asymptomatic individuals (Goode et al. 2008, Vleeming et al. 2008, Vleeming et al. 2012). Hence, the stability of the SIJ is more closely related to how a load can be smoothly and effortlessly transferred across the SIJ than it is related to the degree of mobility. Non-optimal joint stability is defined in the European guidelines (Vleeming et al. 2008) as an “altered laxity or stiffness leading to new joint positioning and/or exaggerated/reduced joint compression, with a disturbed performance/effort ratio.”

**Innervation**

The innervation of the SIJ has been reported in many studies, but there is no agreement regarding the exact innervation of the SIJ (Cohen 2005, Vleeming et al. 2013). In two systematic reviews (Cohen 2005, Vleeming et al. 2013), the innervation of the dorsal part of the joint was suggested to arise primarily from the lateral branches of L4–S3, although different authors have suggested that different levels are involved. The anterior part is assumed to be innervated by the ventral rami, varying from L2 to S4. Further immunohistochemical analyses have been performed on the ventral capsule, interosseous ligaments, cartilage and bone, and there has been evidence of sensory nerves in all of these structures (Szadek et al. 2008, Szadek et al. 2010). The presence of calcitonin gene-related peptide and substance P immunoreactive fibers has been believed to provide morphological and physiological bases for pain signals originating from these structures (Szadek et al. 2008, Szadek et al. 2010), which could be why SIJ injections have effects and might also be why fusion to the joint can be effective for alleviating PGP.

**Referred pain**

Referred pain has been reported to coexist with SIJ pain, and in a study of 25 patients with PGP, verified by positive SIJ injections, as many as 60% had either thigh or leg pain (Laplante et al. 2012). In another study of 50 patients, the authors found
buttock pain in 94% of the patients and referred pain to the leg in more than 50% of the cases but with 18 different pain distributions (Slipman et al. 2000). Before the herniated disc was discovered, the SIJ was regarded as an important etiology of sciatica, and it has been questioned whether nerves can be affected by disturbances in the SIJ (Fortin et al. 1994). Using arthrography, extravasation of contrast agent has been observed in many subjects, and different pathways between the SIJ and neural structures have been identified. Fortin et al. (1994) reported 61% SIJ extravasation in 76 injections, and these cases followed 5 patterns; ventral (16%), dorsal to the first sacral foramen (8%), dorsal sub-ligamentous (24%), superior (3%) and inferior (12%) to the sacral ala. Ventral extravasation of inflammatory agent could theoretically affect the lumbosacral plexus and S1 foramen all the way up to the L5 foramen. The neurotransmitter substance P has been identified as a possible cause of “neurogenic inflammation”. The SIJ is innervated and can therefore be a pain generator. Different referred pain patterns have been observed and can be explained by individual variations in innervation, direct nerve involvement or different sclerotomes (Fortin et al. 1994, Slipman et al. 2000).

**Biomechanical considerations of SIJ movement**

"Interestingly, studies that demonstrated the highest levels of quality and that offered the lowest levels of error in measurement also reported the lowest values [of movement] available at the SIJ."

Adam Goode 2008

As mentioned in the historical overview, several attempts have been undertaken to establish movement in the SIJ, both in healthy subjects and in patients with PGP. Many different techniques have been used, such as cadaver studies, studies using different markers (skin markers, palpation of the bony landmarks and k-wires) and radiological studies (radiography, CT, RSA) (Lavignolle et al. 1983, Sturesson et al. 1989, Brunner et al. 1991, Vleeming et al. 1992a, Jacob and Kissling 1995, Smidt et al. 1995, Smidt et al. 1997, Sturesson 1999, Sturesson et al. 2000a, Sturesson et al. 2000b, Hungerford et al. 2004, Hungerford et al. 2007). All of these techniques have obvious advantages and disadvantages. The cadaver studies lacked muscular influence on stabilization, and the sample tended to come from an older population. The different experimental settings have different levels of precision and accuracy, and it seems that the methods with the best precision have the lowest measured SIJ motion (Goode et al. 2008). Although the literature regarding analysis of movement has reported various results, there are some points on which these reports have generally agreed.

1. Most of the movement in the SIJ is rotational, occurring around all 3 axes but predominantly in the sagittal plane (Sturesson et al. 1989, Brunner et al. 1991, Walker 1992, Mens et al. 1999, Goode et al. 2008).

2. There are different theories regarding the motion of the sacrum relative to the innominable bone and the center of rotation. Because the sacrum is L-shaped and has an irregular surface, and because there is a large variation among subjects, a fixed center of rotation has been difficult to find (Walker 1992). In Figure 6, different theories that have been proposed are presented: (a) sacral tilt with the center of rotation inside the SIJ; (b) sacral rotation with the center of rotation located immediately dorsal to the SIJ; (c) rotation with the center of rotation in front of the SIJ; and finally, (d) translation with no rotation (Alderink 1990). The evidence is not in agreement regarding this subject, but the strongest evidence has supported that the center of rotation is most likely located dorsal to the SIJ as a transverse axis and in close proximity to the iliac tuberosity (Figure 6b) (Egund et al. 1978, Brunner et al. 1991, Vleeming et al. 1992b, Jacob and Kissling 1995), although there are likely large individual differences.

3. The movements in the SIJ are small, and the total rotation has varied in different studies but has seldom exceeded a mean value of 2° (Jacob and Kissling 1995, Egund et al. 1978, Vleeming et al. 1992a, Goode et al. 2008, Vleeming et al. 2012). This movement has seemed to be greater in an unloaded pelvis than in a loaded pelvis (Sturesson et al. 1989, Sturesson et al. 2000a, Sturesson et al. 2000b, Goode et al. 2008).
4. There do not seem to be differences in movement between symptomatic and asymptomatic SIJs (Sturesson et al. 1989).

5. There is evidence that women tend to have greater mobility than men. In healthy volunteers, Jacobs (1990) did not find any differences in SIJ movement with regard to age, sex or parturition. Other studies have reported less movement in men than in women (Brunner et al. 1991, Bussey et al. 2009, Sturesson et al. 1989). It also seems that multiparous women have greater movement of the pelvic joints than nulliparous and men (Garras et al. 2008, Mens et al. 2009).

To measure SIJ movement accurately, the RSA technique has been applied to the SIJ. One-millimeter markers were implanted in patients, and with a specialized x-ray set-up and a computer program, the in vivo movement could be measured with high precision (Sturesson et al. 1989). These markers were attached to a segment in each ilium and to one in the sacrum, and the movement between these segments was then measured (for a more detailed description, see section 4.5). The RSA studies have, in general, reported less movement than other studies using methods with questionable precision (Goode et al. 2008), and because the RSA showed less motion than other methods, the RSA method has been questioned. The RSA studies have measured movement between the sacrum and the ilium with dorsally placed RSA markers, and the markers were placed near the joint line. Because of the flat anatomy of the bones, the markers became collinear (in the same plane, which is not necessarily the optimal 3D distribution of the markers (Cibulka 2001)).

Guidelines for the standardization of RSA of implants have recommended at least three non-collinear RSA markers in each segment (rigid body), which should be compared to one another (Valstar et al. 2005). A good 3D configuration of the segments relies on the distance between the markers and the distribution of the markers on all three axes; a condition number (CN) expresses the quality of a marker segment (Makinen et al. 2004). The CN is a mathematical expression of how the markers relate to a straight line that passes through the segment (Ryd et al. 2000). A low CN represents a good scatter of markers in the segment. A CN below 110 is suggested. This CN will consequently influence the precision and accuracy. Additionally, another factor of importance is how well the RSA computer identifies and calculates the placement of each individual marker. The precision of each marker can be influenced by soft tissue disturbances and by the stability of the markers. If the markers are not thoroughly inserted into the bone and end up in the soft tissue, the markers can become unstable. This instability can occur in the sacrum because of the thick and strong dorsal ligaments covering the bone, particularly in the cranial portion. To ensure including only stable markers in the analysis, unstable markers should be excluded if they move more than 0.35 mm between two examinations (ME; mean error of rigid body fitting) (Valstar et al. 2005). Uncertainties with the RSA method, when applied to the pelvic joints, were addressed in a letter to the editor by Cibulka (2001), in which he asked:

“I question whether using this sort of marker arrangement can accurately define the fixed segments (especially the innominate bones) and therefore truly describe sacroiliac joint motion.”

“Would a different configuration (e.g., wider distribution) of pelvic markers show different results?”

Cibulka 2001

These questions formed the basis for our first research question: What are the accuracy and precision of RSA when applied to the SIJ, and was the marker distribution used in the available RSA studies useful?

**The Chamberlain technique**

“The place to look for evidence of sacroiliac joint motion is at the symphysis pubis, where it is magnified and measurable.”

Chamberlain (cited in Andersson 1944)

All of the experimental techniques used to quantify SIJ movement have been impractical in clinical practice. In 1930, Chamberlain described an easy and practical method for measuring pubic movement on anterior-posterior (AP) pelvic radiographs while the patient stood on one leg with the other leg hanging down (single-leg stance) (Chamberlain 1930) (Figure 7). In patients with SIJ pain, Chamberlain found that weight bearing caused cranial displacement of the pubic bone to the side of the painful joint. This displacement was explained by rotation around the axis that was perpendicular to the SIJ surface. The Chamberlain technique has since been used to examine pubic bone movement and, indirectly, SIJ hyper-mobility (Mens et al. 1999).

Since the Chamberlain technique was first described, researchers have attempted to correlate pubic movement with
SIJ pain (Anderson and Peterson 1944, Mens et al. 1999, Siegel et al. 2008). Chamberlain found a clear pattern in his patients, but Mens et al. (2009) subsequently found the exact opposite pattern, in which the hanging leg caused downward displacement of the pubic bone on the side of the painful joint. These differences have made it difficult for clinicians to use the results of this test in the diagnosis of PGP, particularly when normal variations in the movement of the pubic symphysis have proved to be large (Gurras et al. 2008). Measurements of the movement of the SIJ with the subject in the single-leg stance have been obtained using k-wires; however, those authors only measured healthy subjects without SIJ pain (Jacob and Kissling 1995). Because the Chamberlain technique is an indirect measurement of SIJ movement, what really occurs in the SIJ during the single-leg stance test in patients with SIJ pain (1921–1940), there were mostly descriptions of SIJ movement, what really occurs in the SIJ during the single-leg stance test in patients with SIJ movement. This uncertainty formed the basis for our second research question: What is the movement in the SIJ during the single-leg stance in patients with severe PGP?

SIJ fusion as a treatment for SIJ pain

"Cases of relaxation of the sacroiliac joint which have had the above type of arthrodesis performed have been uniformly successful."

Smith-Peterson 1921

The role of the SIJ as a pain generator has interested orthopaedic surgeons for almost a century. Smith-Peterson described a method for SIJ fusion in 1921 (Smith-Peterson MN 1921), and since then, several different attempts have been made to select and operate on patients with suspected SIJ pain. In the beginning, a large proportion of the patients had joint infections (especially tuberculosis), and many of the first surgical techniques were developed to treat these infections, but patients with “pelvic relaxation” during pregnancy have also comprised a large proportion of the patients receiving SIJ fusion (Smith-Peterson 1921, Smith-Petersen and Rogers 1926, Hagen 1974) (Appendix). SIJ fusion followed the same popularity curve as the knowledge of SIJ movement, most likely because movement, pain and fusion are closely related in an orthopedic surgeon’s mind. If there is mobility that causes pain, fusion can cure the pain. Before the herniated disc was discovered, SIJ fusion was a novel treatment for low back pain and disruption after pregnancy, and the treatment was described in several case series in the period from 1921 to the 1940s (Appendix). After the 1940s, there were no papers in the literature until the 1970s, when new reports of SIJ fusion started to appear. In the last few years, the role of the SIJ in orthopedic surgery has again been gaining popularity.

Almost a century has passed since Smith-Peterson published his experiences with SIJ fusion in 1921. Despite this long history, only a few papers can be found in the literature, and to locate these papers, searches were conducted in Medline/Ovid, Embase and Google Scholar, combining the terms “sacroiliac joint”, “arthrodesis” and “fusion”. From the articles retrieved from this search, all of the articles and references were cross-checked to find further possible evidence. The results included only 30 papers and book chapters (Appendix).

When planning the study in 2005–2006, only 18 papers were available, describing 277 patients and 13 different surgical techniques. Although many different techniques were used, they all involved either open anterior or open dorsal fusion. In the beginning (1921–1940), there were mostly descriptions of these new surgical techniques and short descriptions of the results obtained for the first patients. In these materials, a large proportion of the patients were surgically treated for infections or for SIJ arthritis. The authors reported, in general, excellent to good outcomes in 50–60% of the patients, fair results in 20% and poor results in 20%. No further documentation was found from between 1941 and 1974, likely because the SIJ lost attention to the herniated disc. Until 2006, there were only case series, and only 4 of these 18 series were prospective registrations of outcomes. Only one larger study was available when we started our investigation, and this large study did not actually evaluate SIJ fusion but instead fixation with SIJ screws and without fusion (van Zwienen et al. 2004). All of these studies had short follow-up periods, except for one that had 5.8 years of follow-up (Buchowski et al. 2005). Since 2006, 12 more case series have been published, all of which were designed as retrospective reviews of prospective registered outcome measurements, and these studies are referred to as prospective in the appendix because the outcome measures were collected pre- and post-operatively. These studies reported the surgical outcomes of 354 patients, and all of these reports were the results of minimally invasive surgery (MIS).

The diagnostic criteria and the criteria for surgery are not standardized, and surgery for PGP is controversial. There have been few studies and only limited knowledge about this treatment option (Appendix 1). Hence, it is difficult for healthcare providers to give proper advice to patients with PGP regarding surgery.

History of pelvic joint fusions in Norway

In 1974 orthopaedic surgeon Rolf Hagen, Martina Hansens Hospital, published his experience with conservative and surgical treatment of 23 patients with SIJ pain. Over a 20 year period from 1951–1971, eight patients were operated on with the surgical technique described by Smith-Peterson (Hagen 1974). Six out of these 8 had a good result, 1 had a fair result and 1 did not have any effect at all. From the middle of 1970’s to late 1990’s a few orthopedic surgeons in Norway performed SIJ fusions and some also did fusion to the pubic symphysis. Especially, orthopaedic surgeon Einar Sudmann at Hagavik Hospital, developed a systematic approach to the SIJ problem, as he registered the surgical outcome of 81 patients together with complications in a database. Einar Sudmann and
the rest of the orthopaedic surgeons performing SIJ fusions did however not achieve the results they wanted. Because the outcomes were unpredictable, the complication rate appeared unacceptably high and the need for additional spinal surgery, the enthusiasm diminished. During the 1990’s most orthopedic surgeons had stopped performing SIJ fusions except professor Olav Røise, orthopedic pelvic trauma surgeon at Oslo University hospital. In the early 2000s the medical literature on surgical treatment of PGP was sparse and without high quality studies, and because of this professor Røise decided to stop doing the surgery until a study protocol was established. In 2004 a pilot study with 4 patients was conducted and in 2005 Olav Røise together with Britt Stuge, PT, PhD, Finnur Snorrason, MD, PhD and May Arna Risberg, PT, professor at OUS, started to plan this project.

The lack of documentation regarding the results after SIJ fusion and the fact that Sudmann performed SIJ fusion on more than 80 patients between 1977 and 1998 led us to the last two research questions: What are the outcomes of SIJ fusion, and what are the long-term results after SIJ fusion?

Aims of the thesis

The main questions and aims of the thesis are:

Paper I
Is the RSA method valid to measure pelvic movement?
The aims were to (1) measure the accuracy, precision, and condition numbers of pelvic RSA with different marker distributions in a phantom model, (2) explore whether frontal markers around the symphysis improve the condition number and precision and whether it is possible to avoid markers in the cranial part of the sacrum, and (3) to compare the precision obtained by a phantom with the precision in patients.

Paper II
What is the movement in the SIJ during the single-leg-stance test?
The aims were to (1) measure movement in the SIJs during the single-leg stance test by using RSA, in patients with severe PGP and to (2) identify whether there were any differences between movements in the SIJs of the standing leg and the hanging leg.

Paper III
What is the outcome of unilateral anterior SIJ fusion combined with fusion of the pubic symphysis?
The primary aim of this prospective study was to examine changes in pain and physical function at 3, 6, and 12 months after SIJ fusion. The secondary aims were to evaluate post-operative health-related quality of life and patient satisfaction with treatment.

Paper IV
What are the long-term results of SIJ fusion?
The main purpose was to evaluate long-term functioning, pain and health-related quality of life (HRQoL) in patients who had previously undergone pelvic joint fusion surgery. Further aims were to compare the 1-year outcomes with the long-term results and to compare patients who underwent surgery with PGP patients who did not undergo surgery.
Patients

Papers I, II and III
The patients in papers I, II and III consisted of patients from the same cohort. Originally, we planned to include and operate on 10 patients at Oslo University Hospital, Norway, and 10 patients at Ångelholm Hospital, Sweden, during the inclusion period from 2007 to 2010. In Norway, 20 patients were examined, but only 9 met the criteria for participation (Figure 8). The patients were included according to the criteria provided in Table 2.

In Sweden, 10 patients were also selected for surgery, but unfortunately, there were problems with the collection of questionnaires, primarily due to large administrative changes and the loss of key personnel in the Orthopedic Department at Ångelholm Hospital. Some preoperative and 1-year data were available, but the collection of questionnaires was incomplete. Hence, these patients were excluded from paper III.

All of the Swedish patients, however, had RSA markers implanted and were thus available for the RSA study (paper II). After evaluating the RSA data from all of the patients, six patients were excluded because of poor x-ray quality, so 11 patients were eligible for inclusion in paper II (Figure 8). The patients were excluded because of misplaced markers in the soft tissue or insufficient visualization of the markers on radiographs during the software analysis. In paper I, we were able to use RSA pictures from 6 of the 9 Norwegian patients (Figure 8). The Swedish patients did not undergo double examinations; therefore, they were not included in paper I.

Paper IV
The patients in paper IV were operated on at Hagavik Orthopaedic Hospital between 1977 and 1998 by Sudmann and co-workers. The data came from 50 subjects at 1 year after SIJ fusion and from long-term follow-ups. Eighty-one patients underwent SIJ fusion during this period. These patients were registered in a database and were asked in 2009 to participate in long-term follow-up. The study population is described in Figure 9. During the 1990s, the surgeons became increasingly reluctant to perform SIJ fusion, and a number of patients were refused surgery. Twenty-eight of these patients constituted the non-surgery group.

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Table 2. Inclusion and exclusion criteria

| Inclusion criteria | Exclusion criteria |
|--------------------|-------------------|
| 1. Pain located to one or more pelvic joints | 1. Known psychiatric diagnosis |
| 2. Minimum two positive out of five clinical tests: | 2. Other spine pathology |
| – Posterior pelvic pain provocation test (P4) test | 3. CT-verified ankylosis at baseline |
| – Active straight leg raise (ASLR) test | 4. Body mass index over 30 |
| – Palpation of the long dorsal sacroiliac-ligament | |
The patients were selected and operated on primarily by one of the authors (E.S.). The criteria for surgery were based on the patient history and on radiological and clinical examinations. The inclusion criteria were pain in the SIJ >1 year after pregnancy or trauma, pain with an idiopathic origin, severe disability and resistance to conservative treatment. The clinical tests performed included tenderness at the superior and inferior posterior iliac spines, active and passive straight leg raise tests, Patrick Faber’s test, passive hip rotation, forcible inward rotation and extension of the hip joint. Further tests included normal neurological and gynecological exams, normal spinal x-rays, symphysis movement of less than 3 mm on plain radiographs during a one-leg stance, normal radiculography, negative rheumatology tests and negative blood tests.

Figure 9. Flow chart of patients in paper IV.
Methods

Design

Paper I
In paper I, the accuracy and precision of pelvic RSA were evaluated in an experimental setting using a phantom model, and the precision was also measured in vivo by double examinations. We used a plastic pelvic phantom (Sawbones® 1301; Pacific Research Laboratories, Inc., Vashon, WA, USA) attached to a micrometer to measure the true value of movement, and these values were compared to the values obtained from the RSA measurements. Because the number of markers needed has been questioned, the accuracy and precision were also evaluated with different numbers and distributions of markers.

Paper II
In paper II, we used RSA to measure the in vivo movement of the SIJ in patients with PGP in the single-leg stance.

Paper III
In paper III, a single-subject research design was used to evaluate the individual response and outcomes of pain, disability and health-related quality of life after SIJ fusion. The use of multiple measurements, at baseline and after the intervention, allowed us to consider the patients as their own controls. Five data collection sessions were conducted in each of the following 4 phases: prior to surgery (baseline) and at 3, 6, and 12 months after surgery.

Single-subject research design (SSRD)
A randomized controlled trial is the gold standard for examining the effects of an intervention. Because SIJ fusion is performed on few patients, a single-center randomized controlled design was difficult to apply due to the small number of available participants. Single-subject research designs (SSRDS), however, have been recommended as useful for examining clinical accountability (Engel and Schutt 2009). If properly applied, an SSDR can provide a systematic approach for documenting clinical changes and can also provide evidence regarding the efficacy of a treatment modality (Engel and Schutt 2009). SSRD refers to a study of a single patient or a small number of patients observed over time, during which the treatment and outcome variables are controlled. The design consists of multiple measurements before (baseline) and at different phases after the intervention (Engel and Schutt 2009). The data are then presented graphically with a mean value in each phase, and the changes between the phases are shifts in level (Figure 10).

An SSRD focuses on individual responses and repeated measures, which improve the validity of the study. When an SSRD is replicated across patients, the internal and external validity is strengthened, allowing inferences to be made about effectiveness (Gonnella 1989, Zhan and Ottenbacher 2001, Logan et al. 2008).

Paper IV
Paper IV was a cross-sectional study of the patients who underwent SIJ fusion at Hagavik Hospital in Norway between 1977 and 1998, and the data consist of surgical results 1 year after surgery and over a long-term follow-up. In 2009, all of the eligible patients (Figure 9) received by mail invitations to participate and a questionnaire. The long-term outcomes of the patients who underwent SIJ fusion were compared to those of a semi-matched group of patients who did not undergo this surgery. At 1 year, the surgeon graded each joint as good, fair or poor. The clinical outcomes were graded according to the following criteria. A joint with negative SIJ tests and no or minor pain that did not interfere with the patient’s work was graded “good”. A joint with obvious improvement compared to the pre-operative status and little pain but with pain that interfered with work (professional or at home) was graded “fair”. A joint was graded “poor” if there was no relief from pain or if the joint deteriorated after surgery. In cases of bilateral surgery, each of the patient’s joints could receive a different grade. According to the grading of the joints one year...
after surgery, the patients were allocated to three different subgroups (Figure 11).

Twenty-four patients (48%) had all of their joints classified as “good” and were assigned to the “successful” subgroup. Fourteen patients (28%) had at least one joint classified as “poor” and were assigned to the “unsuccessful” subgroup.

Twelve patients (24%) had their worse joint scored as “fair” and represented the “partly successful” subgroup (Figure 11). These three subgroups formed the baseline for comparing the long-term effects. The patients’ 1-year outcomes were prospectively registered in a DOS Advanced Revelation relational database by the surgeons responsible for the operations.

**Data collection**

### Papers I, II and III

The patients in papers I, II and III were included after a baseline evaluation. At baseline, a clinical evaluation was performed, and the patients completed questionnaires. It has previously been shown that female patients with PGP have variations in pain intensity during the menstrual cycle, with a relapse around menstruation (Mens et al. 1996). For this reason, the patients completed a questionnaire every Thursday for 5 weeks during each phase, to ensure that the evaluations were performed throughout the entire menstrual cycle (Figure 12). The questionnaires were returned weekly by mail. All of the patients underwent 3 clinical examinations, and in all but two cases, CT-guided SIJ injections were administered before the decision to perform SIJ fusion was made. The CT-guided injections were administered by two experienced radiologists, and the patients filled out a VAS scale before and at 2 hours after the injections. The SIJ injections were not used as inclusion criteria but rather as one of several factors to strengthen the diagnosis before surgery. The patients underwent surgery to fuse the more painful SIJ, and the pubic symphysis was operated on in all of the cases.

RSA images were obtained pre-operatively and after 3, 6 and 12 months, but the pre-operative images were used in papers I and II because a pre-operative clinical test (single-leg stance) was evaluated.
Paper IV
In paper IV, the patients received a similar questionnaire to that of the patients in paper III. They completed it and returned it in a pre-paid envelope.

Outcome measures
In papers III and IV, the patients completed a questionnaire consisting of the Norwegian versions of the Oswestry disability index (ODI), a visual analog scale (VAS) and the short form-36 (SF-36). Our main outcome was the ODI, and the secondary outcomes were the VAS, the SF-36 and self-reported satisfaction with treatment. In paper III, the patients also registered their pain distribution on a pain diagram.

Oswestry disability index (ODI)
The ODI was initiated by John O’Brien in 1976, and it has become one of the most commonly used condition-specific outcome measures for patients with LBP (Fairbank and Pymsent 2000). The questionnaire measures limitations in various activities of daily living, and the disability is graded using 10 items, for a total score ranging from 0 to 100. Each item consists of 6 statements, and these statements are scored from 0 to 5, with 0 indicating normal function and 5 a grade of high disability. A maximum score of 50 can be achieved, and this score sum is doubled and expressed as a percentage. A high score indicates a high grade of disability, and a 10-point difference represents a significant clinical change (Fairbank and Pymsent 2000, Hagg et al. 2003). The Norwegian version of the questionnaire was used (Grotle et al. 2003). The ODI was tested for test-retest reliability, and at 24 hours, the reliability was 0.99. When the interval was increased to 4 days and one week, the test-retest reliability values were 0.91 and 0.83, respectively (Fairbank and Pymsent 2000).

Visual analogue scale (VAS)
Each patient’s most severe morning and evening pain intensity was assessed using a 100 mm VAS (0=no pain, 100=worst possible pain) (Revill et al. 1976). The patients answered two questions: (1) How severe is your pain in the morning, immediately after you leave your bed? and (2) How severe is your pain in the evening, immediately before you go to bed? The VAS was found to be sensitive to changes in pain intensity, and it has been validated for this use (Hagg et al. 2003, Von et al. 2000).

Pain diagrams
In addition to the VAS, a pain diagram was used to localize the pain and pain referrals (Figure 13), and when used as a pain locator, it has shown reliable results (Ohlund et al. 1996). The patients were asked to draw a cross where they experienced pain.

Short form-36 (SF-36)
Health-related quality of life was assessed using the Norwegian version of the SF-36 (Loge et al. 1998). This questionnaire is divided into 8 sub-scales: physical function, physical role, bodily pain, generic health, vitality, social function, emotional role and mental health. The score is converted to a 0–100 scale for each of these 8 items, and a high score indicates good health status.

Self-reported satisfaction with treatment
Additionally, the patients answered the following two questions: “Have you experienced any effects of the surgery? If so, would you grade these effects as excellent, good, some, minor or no effects?” and “How do you tolerate physical activity now, compared to before surgery?”

Surgical intervention
All of the patients in paper III received unilateral SIJ fusion combined with symphysiodesis. An anterior approach with a skin incision over the iliac crest was used to reach the SIJ. The joint was partially resected, and the bone was grafted with cancellous bone from the ipsilateral iliac crest. Two AO (Arbeitsgemeinschaft für Osteosynthesefragen) reconstruction plates or AO-DC plates (Synthes®, Synthes GmbH, Switzerland) were used (Figure 14) to achieve stabilization. The pubic symphysis was accessed through a bikini line incision. A 2 × 2 cm bone block was removed and replaced with a bone graft from the iliac crest, and a Matta plate was applied (Figure 14). Post-operatively, the patients received epidural anesthesia pain relief and 1–2 days of wound drainage. The
patients were advised to avoid full weight-bearing activities for 8 weeks after the surgery.

The patients in paper IV were operated on using a dorsal approach, with either trans-iliac fusion or intra/extra-articular fusion between the ilium and the sacrum. When the trans-iliac fusion was performed, an iliac window was constructed to access the joint (Smith-Peterson 1921). The joint surface was cleared of cartilage and was decorticated. The cortical iliac window was used as a graft and was typically hammered into the sacrum to promote intra-articular bone formation and conduction. Additional cancellous bone was compacted around the cortical graft. In dorsal intra/extra-articular fusion, iliac crest autografts were added after joint removal and bone decortication (Waisbrod et al. 1987). The pubic symphysis was fused in four patients using an open technique, with an iliac crest block bone autograft and plating.

Radiostereometric analysis (RSA)

RSA was invented by Selvik in 1974 and has primarily been used to measure the 3-dimensional motion of implants and to obtain measurements of implant wear. Small tantalum (1 mm) markers were implanted into the bone segments under general anesthesia through a small skin incision in the dorsal part of the sacrum and in both ilia.

Both in the phantom and in the patients, approximately 8 markers were inserted into each bony segment (Figure 15), and the movement between these marker segments was later measured. The calibration cage contained markers, so the markers in the patients could be assigned to a 3D coordinate system (Figure 16). Two to 3 weeks after RSA x-rays were obtained with two angulated x-ray tubes (approximately 40°). The x-ray films were placed behind a calibration cage (Figure 17).
**Accuracy and precision of the pelvic RSA**

**Paper I**

A good 3-D configuration relies on the distance between the markers and the distribution of the markers on all three axes, and a condition number (CN) expresses the quality of a marker segment (Makinen et al. 2004). Guidelines for standardization of the RSA of implants have recommended at least three noncollinear markers in each segment (rigid body) (Valstar et al. 2005). The CN is a mathematical expression of how the markers relate to a straight line passing through the segment (Ryd et al. 2000). A low CN represents a good distribution of markers in the segment. A CN of less than 110 is considered a reliable distribution (Valstar et al. 2005), and an upper limit of 150 has been recommended. The CN will influence the precision and accuracy, and a factor of importance is how well the RSA system calculates the placement of each marker. The precision of each marker can be influenced by soft tissue disturbances and by the stability of the markers. If the markers are not thoroughly inserted into the bone and are partially or completely in the soft tissue, the markers can become unstable. This instability can occur in the sacrum because of the thick and strong dorsal interosseous ligaments covering the bone, particularly in the cranial part. Unstable markers should be excluded if they move more than 0.35 mm between two examinations (mean error [ME] of rigid body fitting) (Valstar et al. 2005).

The accuracy and precision of RSA have been tested in different settings and have been reported to be high. Despite the use of pelvic RSA in clinical research, the accuracy and precision have not been fully evaluated. The accuracy of the measurement is the closeness of the measurement to its true value. In phantom models, accuracy reflects the level of agreement between the true value of movement and the results obtained using RSA. Systematic error (bias) of the system occurs when the differences between systems and experiments are uniform (Ranstam et al. 2000). In paper I, the true value of movement was measured with a phantom attached to a micrometer (Figure 18), and these values were compared to the measurements from pelvic RSA. This value should ideally be zero.

The precision (spread) of the measurement is the degree of closeness of repeated measurements under unchanged conditions. Under optimal conditions, the difference between two examinations should be zero (Ranstam et al. 2000). The precision was measured in the phantom model and was evaluated in the patients using 17 double examinations in six patients.

To evaluate the difference of different marker distributions on accuracy and precision, the eight markers in each segment were divided into four different marker segments (Figure 19). We wanted to determine whether the markers in the pubic symphysis could increase the precision and how many markers were needed in each segment to achieve precision and accuracy. To examine the need for frontal markers, we performed tests with and without frontal markers. To examine the need for cranial markers in the sacrum, we performed tests with and without these markers. Finally, three dorsal markers in the ilium and three cranial markers in the sacrum were randomly selected (Figure 19) and were tested against eight markers.

In paper II, three pairs of images were obtained: one with the subject standing on both feet, one with the subject standing on the right foot and one with the subject standing on the left foot (Figure 20). The sacrum was defined as the fixed segment, and the movement of the innominate bone was relative to the sacrum.
Figure 20. RSA setup. A. Patient standing on both feet. B. Patient standing on left leg with the right leg hanging down. C. Patient standing on right leg with the left leg hanging down.
Main results

Paper I

Overall, the RSA method applied to the SIJ was found to be accurate and to have high precision.

Accuracy

When we applied translations and rotations to the micrometer, the RSA had good ability to detect these movements. With 8 markers in both the sacrum and ilium, the mean accuracy was between -0.03° and 0.05° for the rotations (Table 3). For translation, there was a small underestimation in the Z-direction of 0.07 mm. The resolution of the micrometer was 0.04° and 0.01 mm; therefore, these deviations from zero were not sufficiently large to be considered a systematic error that required correction.

Precision

For the RSA measurements in the phantom, there was high precision in all of the analyses, from 8 markers in each segment down to 3 markers in each segment. The precision (LOS) in the phantom was between 0.06° and 0.25° for rotation and between 0.03 mm and 0.16 mm for translation with 8 markers in each segment; with 3 markers in each segment, the precision was between 0.14° and 0.26° and between 0.09 mm and 0.21 mm. The precision in the patients was lower than in the phantom, with precision for rotation between 0.2° and 0.7° and for translation between 0.3 mm and 0.5 mm.

Analysis of different marker distribution and numbers of markers

The CN in the phantom varied from 17 to 59 in the sacrum and from 29 to 117 in the ilium, with varying numbers of markers and different marker distributions. When the markers placed in the symphysis were removed from the phantom, the CN increased from 29 to 92. The ME was reduced (p = 0.001) when the frontal markers were removed. There was no difference in the accuracy, but the precision decreased from 0.06° to 0.22° in the Z rotation (p = 0.010) and from 0.08 mm to 0.18 mm in the X translation (p = 0.003). In vivo, the removal of the frontal markers did not affect the precision. The CN in the ilium increased from 38 to 96 (p = 0.001), and the ME had a tendency (p = 0.048) to be lower in the ilium without the frontal markers. When the two cranial markers were removed, there was a reduction (p = 0.012) in the accuracy of the Y translation from -0.03 mm to -0.01 mm, and the precision was reduced from 0.11° to 0.22° in the Z rotation (p = 0.023), as well as in the X translation (p = 0.005), where it decreased from 0.08 mm to 0.24 mm. When three randomly selected markers were analyzed compared with eight markers, there were reductions in the precision of the Y and Z translations (p = 0.016 and p = 0.013, respectively), but there was no reduction in accuracy.

Table 3. Accuracy of the phantom

|                      | Bias (mm) | SD_{bias} | 95% CI          |
|----------------------|-----------|-----------|-----------------|
| Rotations            |           |           |                 |
| X                    | -0.025    | 0.128     | (-0.106 to 0.056) |
| Y                    | 0.051     | 0.039     | (0.026 to 0.076)  |
| Z                    | 0.003     | 0.021     | (-0.011 to 0.016) |
| Translations         |           |           |                 |
| X                    | -0.003    | 0.042     | (-0.024 to 0.018) |
| Y                    | -0.012    | 0.028     | (-0.027 to 0.003) |
| Z                    | 0.065     | 0.023     | (0.016 to 0.115)  |

Accuracy expressed by bias; Bias = mean of the difference between the true value (TV) and the measured value (MV); SD_{bias} = standard deviation of the difference between TV and MV; 95% CI = 95% confidence interval for the bias.

Paper II

Eleven patients (4 from Norway and 7 from Sweden) with long-term PGP were analyzed. Only small movements in the SIJ were detected, and only 15% of the measurements exceeded the precision of the RSA. Although some of the mean values were significantly different from zero, all but one of these mean values was less than the precision of the RSA.

The main findings in this study were as follows.

- When the patients performed a single-leg stance, there was almost no detectible movement.
- There was a mean of 0.5° of rotation on both sides around a helical axis (the true axis of rotation).
- When the movements were assessed based on the coordinate system (Figure 16), a small, 0.3° (SD 0.2) rotation around the Z-axis in the SIJ of the standing leg (p < 0.001) was observed. This rotation was significantly different from that of the hanging-leg SIJ (p = 0.036).
- No translations were detected.
- With the exception of the 0.2° difference observed in the Z-axis rotation (p = 0.036), no differences were observed in the movement between the SIJs of the standing leg and the hanging leg (p-values between 0.055–0.978).
- There were no differences between the 18 symptomatic joints and the four asymptomatic joints with regard to the total amount of rotation (diff: -0.2, p = 0.335 on the standing side; diff: 0.0, p=0.896 on the hanging side) or translation (diff: -0.1, p = 0.398 on the standing side; diff: 0.1, p = 0.687 on the hanging side).
Nine consecutive patients received unilateral anterior SIJ fusion with concomitant fusion of the pubic symphysis. One patient developed chronic fatigue syndrome during the follow-up and dropped out of the study after 6 months. The remaining eight patients followed the study protocol; the baseline characteristics of these patients are presented in Table 4.

The ODI scores for each patient are presented in Figure 21. All but one patient exhibited a decrease of more than 10 points on the ODI from the pre-operative period to the 1-year follow-up. One patient experienced no effects. There was a strong association between ODI and time, with a 17-point decrease (p < 0.001) at 1 year after surgery (Figure 21). The graphs showed significant variations in the measurements at each time point. At baseline, a difference of more than 40 points between the maximum and minimum values was observed in two patients, and only two patients had less than a 10-point difference.

The VAS scores of each patient are presented in Figure 22. The patients experienced a reduction in pain, with a decrease from 82 points at baseline to 57 points after 1 year (p < 0.001, regression coefficient of -8.4) (Figure 22). All of the patients reported a decrease in pain. Pre-operatively, a difference of 43 points between the maximum and minimum values was observed in one patient, and none of the patients had variations of less than 10 points.

At baseline, seven of eight patients had bilateral SIJ symptoms. At the 1-year follow-up, only two patients experienced pain in the fused joint; however, six of the seven patients reported discomfort on the contralateral side. Seven patients had pain in the pubic symphysis before surgery, and five continued to have pain in this area at the 1-year follow-up.

On the SF-36, the patients experienced a mean 20-point improvement in physical function and bodily pain (p < 0.001), a 15-point improvement in social functioning (p = 0.008) and a 6-point improvement in general health (p = 0.009).

All of the patients reported that the surgery had positive effects; one patient reported minor effects, two reported some effects, and five reported good effects of the surgery. None of the patients reported excellent results. With regard to tolerance of physical activity, seven patients reported some improvement, and one patient reported major improvement.

There were 3 major complications: one infection, one case of complex regional pain syndrome with drop-foot and one loss of bladder sensation. There were also 3 cases of transient sensitivity loss of the lateral femoral cutaneous nerve as a pos-
sible complication of bone harvesting from the iliac crest. All of the patients reported high post-operative pain levels, and they required epidural treatment for 5–7 days. They were hospitalized for 7–10 days and were discharged with prescribed opioids.

**Paper IV**

The demographics of the patients who did and did not undergo surgery are presented in Table 5. The non-surgical group was younger and had a shorter follow-up period than the surgical group.

The patients who underwent surgery had a mean ODI of 33 (95% CI 24–42) and an evening VAS of 54 (95% CI 46–63) 23 years after SIJ fusion (Table 6). The subgroup of patients with a successful 1-year outcome had significantly lower scores on the ODI and the VAS than the patients with unsuccessful outcomes at 1 year. There was a 16 point difference in ODI score between these two groups, and this difference was regarded as both clinically and statistically significant (p=0.034). The difference in VAS between these two groups was 28 (p=0.011). There were positive correlations between the 1-year outcome and three different long-term outcomes; VAS in the morning (ρ = 0.34, p = 0.0016), VAS in the evening (ρ = 0.42, p = 0.013) and ODI (ρ = 0.43, p = 0.002). There were no significant differences in ODI (ρ = 0.54), morning VAS score (p = 0.54), evening VAS score (p = 0.50) or SF-36 score between the group that underwent surgery and the non-surgery group at the long-term follow-up.

Table 5. Characteristics of the participants in the long-term follow-up study

|                | Surgery group (n=50) | Non-surgery group (n=28) | p-value |
|----------------|----------------------|--------------------------|---------|
| Age (years)    | 58 (56–61)           | 52 (49–55)               | 0.003   |
| Follow-up (years) | 23 (22–24)       | 17 (16–18)               | 0.08    |
| Male/female    | 3/47                 | 0/28                     | 0.8*    |
| Etiology       |                       |                          |         |
| Pregnancy      | 60%                  | 68%                      |         |
| Trauma         | 16%                  | 14%                      |         |
| Idiopathic     | 24%                  | 18%                      |         |
| Disability pension | 0%            | 28%                      | 0.9*    |
| 0–50%          | 30%                  | 28%                      |         |
| 50–99%         | 16%                  | 18%                      |         |
| 100%           | 54%                  | 54%                      |         |
| Pain medication| 28%                  | 11%                      | 0.3*    |
| None           | 28%                  | 11%                      |         |
| Seldom         | 10%                  | 18%                      |         |
| 1-6 days/week  | 16%                  | 21%                      |         |
| Daily          | 46%                  | 50%                      |         |

The means are presented with a 95% confidence interval. Comparisons were performed with a two-sample t-test. p-values marked * were tested with a chi-squared test.

Table 6. Results of Oswestry disability index, visual analogue scale and SF-36. Values are adjusted means (95% CI)

|                              | All patients with SIJ fusion (n=50) | The 3 subgroups with different short-term outcomes | Non-surgery group (n=28) |
|------------------------------|-------------------------------------|--------------------------------------------------|--------------------------|
| Oswestry disability index (ODI) | 33 (24–42)                         | 27 (20–34)                                       | 37 (31–43)               |
| Morning VAS score            | 44 (31–57)                         | 38 (27–49)                                       | 42 (31–48)               |
| Evening VAS score            | 54 (46–63)                         | 42 (31–53)                                       | 60 (46–74)               |
| SF–36 | Physical functioning   | 45 (36–54)                         | 56 (45–68)                                       | 47 (30–63)               |
| Physical role                | 25 (12–37)                         | 27 (9–44)                                        | 31 (5–56)                |
| Bodily pain                  | 39 (32–47)                         | 46 (36–55)                                       | 42 (28–56)               |
| General health               | 55 (48–63)                         | 55 (46–64)                                       | 53 (40–66)               |
| Vitality                     | 46 (40–53)                         | 49 (41–57)                                       | 51 (40–62)               |
| Social functioning           | 62 (54–71)                         | 65 (56–75)                                       | 69 (56–83)               |
| Emotional role               | 63 (49–76)                         | 61 (44–79)                                       | 66 (41–92)               |
| Mental health                | 73 (67–79)                         | 72 (64–80)                                       | 76 (64–87)               |

Scores for ODI (0 indicates no disability, 100 indicates a high degree of disability), visual analogue scale (VAS; 0 indicates no pain, 100 indicates the worst possible pain) and SF–36 (0–100; 100 indicates the best health-related quality of life). The means are presented as least-square means, as they were adjusted for body mass index, age and time at follow-up.
Discussion

Methodological considerations

Study designs and patient selection

The study design and the patient selection are important for drawing scientific conclusions from studies and, furthermore, to make the results generalizable. When these subjects are discussed, the terms internal and external validity are often used, and these terms address different quality aspects of the study. Internal validity is e.g. the extent to which the observed effect of an intervention can be explained by the treatment itself, rather than by chance or other systematic errors. Internal validity must be good to be able to draw conclusions that can be generalized (van der Worp et al. 2010). The study must be reproducible and reliable, and any form of bias should be minimized. External validity, in contrast, is the extent to which the results can be generalized.

Paper I

Paper I reported a methodological study in which we used a phantom model to attempt to explain what occurs in vivo. The external validity of a phantom model study can be questioned because the results from a phantom study cannot be transferred directly to the analysis of patients. Therefore, we analyzed precision in both the phantom and in patients. When the 3D position of each individual marker was calculated, the soft tissue was an important factor that could disturb x-rays, and the markers were likely not as stable in patients as in the phantom. These factors rendered the measurements in patients less accurate and less precise. Hence, patient precision should always be determined by double examination. We used a micrometer as the “gold standard” or true value. This micrometer had a resolution of 0.04° and 0.01 mm. The accuracy was less than 0.07 mm for translation and 0.05° for rotation; better resolution would be required to allow the conclusion that this deviation constituted actual bias (systematic error). The bias measured in our study was small and could be explained by the resolution of the micrometer. An interpretation of this bias might be that the RSA method had no bias that had to be corrected for when the measurements were obtained.

As expected, the precision was better in the phantom than in the patients. In the patients, the precision of the rotations had an LOS of less than 0.7° in all directions, and the precision of the translations was less than 0.5 mm. These values were comparable to the precision measurements reported by others (Tullberg et al. 1998, Sturesson et al. 2000b). The RSA method has been widely used in the study of hip prostheses. Using double examinations, precision has been reported to be between a low of 50 µm and 150 µm (Bragdon et al. 2002). When RSA is used in the SIJ, the segments are large, although the spread of the markers occurs mostly along a craniocaudal straight line in the ilia. However, the distance between the segments (sacrum and ilium) is larger than in the analysis of the implants. Abdominal and pelvic soft tissue can also decrease the quality of marker visualization on radiographs. Furthermore, absolutely zero motion between two examinations can hardly be expected. Because the patients were allowed to move between examinations, it is possible that the joints might have aligned differently between the two examinations. Hence, when precision is evaluated in patients, the joint alignment must be considered. All of these factors could explain why the precision was lower than the numbers reported in the analysis of the implants.

We evaluated the RSA in our lab with our set-up and equipment. One could argue that this evaluation weakened the external validity. However, the software that we used had the ability to compensate for the deviation automatically because it retrograde-calculated the positions of the tubes depending on the control markers in the calibration cage. As long as the same software is used, our results should be transferable to other studies as well.

Paper II

We believe the internal validity of measuring movement in the SIJ during the single-leg stance to be good. Both the method and the patients were well described, and the study could easily be replicated. We knew about the high accuracy and precision from paper I, and we did not find any bias for which we had to correct. We also included patients suffering from clinically verified severe PGP; hence, we believe these results to be sustainable.

External validity might have been influenced because only 11 patients were included. They were, however, recruited from two different clinics, and the results were uniform between the two clinics, strengthening the validity of our results.

Paper III

The study design is an important factor in strengthening internal validity. In a prospective registration with repeated measures, such as an SSRd, some of the threats to internal validity can be controlled. Recommendations have been made to rate the quality of an SSRd, and a 14 question checklist was developed to obtain a quality rating (Logan et al. 2008). According to this quality rating, a study can be categorized as strong if more than 11 out of 14 questions can be answered in the affirmative. The 14 questions are divided into five different items:
descriptions of the participants, independent variables, dependent variables, design and analysis.

First, the participants should be well described to enable replication of the study. There are no defined criteria to select patients for SIJ fusion. The diagnosis of PGP is mostly based on medical history and a combination of different clinical tests (Vleeming et al. 2008). Radiological examinations are primarily used to exclude serious pathologies that could explain the symptoms, and SIJ injections are administered to attempt to establish evidence for the SIJ as the origin of PGP. In our inclusion criteria (Table 2) we used the medical history of pelvic joint pain, a combination of 5 different clinical tests, a high level of disability measured by the ODI and a high level of pain measured by the VAS. In addition, the patients had to have undergone conservative treatment without positive effects. We did not include the SIJ injection among the inclusion criteria because there is uncertainty about the diagnostic value of SIJ injections, particularly when this procedure is performed infrequently (Simopoulos et al. 2012). We performed SIJ injections in most of the patients, and the results might have influenced the final decision regarding whether to perform surgery as the effect of the injection was not blinded for the research team. Similar inclusion criteria have been used in many of the studies published in recent years. Hence, we believe that our study can be reproduced, and furthermore, the results can be compared with those of other studies in which SIJ fusion is performed (Rudolf 2012, Cummings and Capobianco 2013, Endres and Ludwig 2013). Concerning the first item regarding description of participants, one point could be added to the total score.

The next two items on the checklist consisted of six questions about independent and dependent variables. The intervention was well described in our study and could be easily replicated. We also believe that the independent variables were well defined because a thorough presentation of the patients was undertaken. The dependent variables are well known and described. The ODI, VAS and SF-36 have been tested for test-retest properties, and the questionnaires have been evaluated for use in the Norwegian population (Loge et al. 1998, Grotle et al. 2003). To score six of six points on these questions, the assessors had to be unaware of the phases of the study, and in our study, we had no opportunity to comply with this requirement. Both the patients and the examiners were fully aware of the phase in which they were. The last quality criterion in item covering the dependent variables was the stability of the measurements. Our patients did not show stability of measurements during any phase. Patients with PGP have reported cyclic variations in symptoms, and as many as 72% report relapses during menstruation (Mens et al. 1996). To account for these potential variations, we repeatedly collected the patients’ data for a 5-week period and discovered a large variation in the values during each phase. For some patients at baseline, a 40-point difference in the ODI and a 43-point difference in the VAS were observed over the 5-week period. Although the stability of the measurements is important for internal validity, one strength of an SSRD is its ability to detect these individual variations, which is important for studying patients with PGP. Some of these variations could be corrected for in large group studies, but conclusions from small case series, with single measurements, should be interpreted with caution because these threats to the internal validity cannot be controlled. Another finding that strengthened the validity of this study was that we measured both morning VAS and evening VAS. Patients with PGP have reported experiencing more pain in the evening than in the morning (Stuge et al. 2004b), and we found a difference of more than 20 points in the VAS between the morning and the evening. Furthermore, the evening pain showed a greater decrease between baseline pre-operatively and at 1 year of follow-up. Hence, when the VAS score is used, this variation must be taken into consideration. According to the SSRD quality checklist, our study scored 4 of 6 points in the questions regarding independent and dependent variables.

The next item covers the description of the design. The study was conducted according to guidelines for SSRDs (Zhan and Ottenbacher 2001, Grotle et al. 2003, Engel and Schutt 2009), and an adequate number of participants (more than 3) was investigated. To score the maximum on this item, the effect should be observed in three or more subjects, and in our study, 7 of 8 experienced positive effects of the intervention. Because all of the questions on this item were answered affirmatively, 3 more points could be added for a total score of maximum 14.

The last item covers the analysis of the data. We presented the data according to the guidelines, and because we had 8 patients, we were also able to conduct a statistical analysis of the whole group. All 4 of the criteria concerning analysis of the data were met, and the total of the SSRD rating was 12 of 14, which is regarded as strong quality by the authors of the rating system (Logan et al. 2008).

One other threat to the internal validity, which is not addressed in the rating, is that the observed results were normal variations in symptoms, and there was another event between baseline and follow-up that could explain this effect. The patients had a chronic condition with mean 11-year duration, so we believe the baseline phase was representative of the pre-operative status. To correct for events in between that could explain the measured effect, we obtained measurements in 3 post-operative phases.

With an SSRD, the findings are generalizable if the study is replicated among 3 or more subjects (Logan et al. 2008). The patients included in papers I, II and III had severe PGP, and they had symptoms from the pelvic girdle for an average of 11 years. They had a mean baseline ODI value of 54, a mean morning VAS of 60 and a mean evening VAS of 82, and only patients with an ODI greater than 40 and/or a VAS greater than 50 were included. Hence, this was a selected group of patients with PGP. In comparison, patients with PGP in the
weeks after pregnancy were reported to have an ODI of 42 and an evening VAS of 58 (Stuge et al. 2004a). The patients reported by Stuge et al. (2004a) did not reach a chronic phase and responded well to conservative treatment. Our patient selection was undertaken by applying strict inclusion criteria, and lumbar spine pathology was excluded by lumbar MRI. Hence, we believe that these patients were representative of patients with severe and long-lasting chronic PGP. The results, however, should be interpreted with the knowledge that these patients were a selected group of patients.

A randomized controlled trial is the gold standard for examining the effects of an intervention, and an understanding has developed that only group studies can produce scientific data (Gonnella 1989). Because SJJ fusion has been performed on few patients, a single-center randomized controlled design was difficult to establish due to the small number of participants. However, a single-subject research design (SSRD) has been recommended as a useful method for examining clinical accountability (Zhan and Ottenbacher 2001). When an SSRD is replicated across patients, the internal and external validity is strengthened and allows inferences to be made about effectiveness. Pelvic fusion in patients with PGP is a rare procedure and is only performed in severe cases in which conservative treatment modalities have been unsuccessful. A randomized controlled trial of this procedure was difficult to perform because the alternative treatment modality (conservative treatment) had already been attempted by most of the patients. Hence, compliance in such a conservative group could have been a great challenge. Because an SSRD with multiple measurements is designed to study small samples of patients, this design was chosen. A limitation of our study was the short follow-up period of 1 year, which is regarded to be too short for a clinical trial, but in paper IV, we reported that the 1-year outcomes after SJJ fusion were sustained 23 years later. Hence, a 1-year follow-up might be sufficient. Despite the limitations of the SSRD, we believe that our study contributes valuable information regarding the effects of pelvic joint fusion.

**Paper IV**

The design of the study in paper IV was cross-sectional and included 50 patients with SJJ pain who underwent SJJ fusion, combined with a long-term follow up. The 1-year outcomes were compared to outcomes recorded in 2009 and to a comparison group. To compare the 1-year results, a sub-group classification was created (Figure 11), and we were aware of the limitations of this subgroup classification. The sub-grouping might not have been optimal, although the post-operative joint pain was classified according to specific criteria. The primary aim of the study was to examine the long-term outcomes of SJJ fusion, not to evaluate the effects of the surgery compared to a control group. There was great selection bias in the two groups. First, they differed in age and length of follow-up, and second, they most likely did not have the same baseline status in pain and function. The comparison must be interpreted with these limitations in mind.

We found a correlation between the 1-year results and the long-term results. With the same inclusion criteria and the same surgical technique, these results could be generalized to this population. With a long-term follow-up, there are several opportunities for bias. We only examined 50 patients, and because the follow-up was as long as 23 years, some of these patients could have experienced other events that would explain the findings.

**Outcome measures**

Because PGP is a multi-factorial condition, a questionnaire should address different aspects of the patient’s experience. To detect changes in pain, disability, and health-related quality of life, we used three different questionnaires: the ODI, a VAS and the SF-36. There are several generic instruments that measure pain perception, functional disability and health-related quality of life, but when we started this project, no condition-specific questionnaire was available (Stuge et al. 2011). Because PGP is a subtype of low back pain with a unique clinical presentation (O'Sullivan and Beales 2007), a condition-specific questionnaire, the Pelvic Girdle Questionnaire, was later developed (Stuge et al. 2011). The closest to a condition-specific questionnaire that was available were the ODI, the Quebec Back Pain Disability Scale and the Roland Morris scales, and these instruments have frequently been used in research on PGP (Vleeming et al. 2008). We used the ODI because most studies have used this questionnaire to investigate interventions in PGP, and it has been shown that the ODI is an appropriate instrument to measure changes in functional status in patients with chronic LBP (Grotle et al. 2004).

We decided to use a VAS instead of a numeric rating scale because most of the studies used this outcome measure after SJJ fusion (Keating et al. 1997, Schutz and Grob 2006, Ziran et al. 2007). A numeric rating scale would most likely have been better than a VAS to detect changes in chronic patients (Grotle et al. 2004), because the responsiveness has proven to be better for NRS compared to VAS when these scales are used on chronic patients. In addition to the VAS, a pain diagram was used to localize local pain and its referrals; for this use, the pain diagram has shown reliable results (Ohlund et al. 1996).

As a generic instrument, we used the SF-36, which has also been used in the evaluation of patients undergoing SJJ fusion (Buchowski et al. 2005). The Norwegian versions of the questionnaires have been evaluated, and they have sufficient properties with regard to validity, reliability and responsiveness (Loge et al. 1998). With the selection of these outcome measures, we first hoped to detect possible changes in pain, physical function and health-related quality of life after SJJ fusion, and second, we were able to compare our results to the available literature.
The SIJ

Movement in the SIJ

The literature has disagreed regarding the amount of movement that occurs in the SIJ, with reports ranging from movement that can be detected by an examiner (Hungerford et al. 2007) to RSA studies demonstrating almost no movement (Sturesson et al. 1989, Sturesson et al. 1997, Sturesson et al. 1999, Sturesson et al. 2000b, Sturesson et al. 2000a, Tullberg et al. 1998). The first aim of thesis was to determine whether the RSA was reliable (paper I). In the phantom model, we measured the accuracy and did not find any bias that had to be corrected for when this examination was used. In the patients, the RSA had a precision for translation of less than 0.5 mm in all directions, and for rotation, the precision was less than 0.3° around the Y and Z axes and 0.7° around the X axis (Figure 16). We also discovered that the markers only needed to be placed in the dorsal part of the pelvis and that 3-4 markers were sufficient if the marker distribution was good (appropriate three-dimensional distances between the markers). We found the RSA technique to be highly accurate and precise. We therefore concluded that the RSA results were reliable and valid because these reports used the same set-up. Nevertheless, some questions regarding the SIJ movements should be addressed.

What is the movement in the SIJ?

There has been evidence that, during and after pregnancy, movements are increased in the pelvic joints and that patients with pain have greater movement than asymptomatic controls (Mens et al. 2009). However, the importance of SIJ movement when patients develop chronic PGP is more uncertain. Some RSA studies have been performed, and the overall findings were that the movement in the SIJ is small, and it seems to be normally distributed (Sturesson et al. 1989). When changing from a supine to a standing position, a total of 1.2° of forward rotation of the sacrum has been reported relative to the innominates, and the movement is 1.6° when the patients change from a supine to a sitting position (Sturesson et al. 1989). In the standing position, the SIJ seems more or less locked. Using RSA, Sturesson et al. (2000b) found a total of 1.2° of rotation in each SIJ when alternating among the straddle position, standing with the left hip maximally extended and right hip maximally flexed and standing with the right hip maximally extended and the left hip maximally flexed. When these authors analyzed the movement during the standing hip flexion test (movement between standing on both feet and standing on one foot with the other hip maximally flexed), a small total movement of 0.6° was reported (Sturesson et al. 2000a). This finding contradicted those of Hungerford et al. (2007), who stated that the SIJ movement could be felt by hand during the Stork test. In addition, Sturesson et al. (1989) did not find any differences in movement between symptomatic and asymptomatic SJs. Hence, there is movement in the SIJ, but there does not seem to be hyper-mobility of the SIJ in patients with chronic PGP (Hungerford et al. 2007, Sturesson et al. 1989).

If the SIJ has a limited range of motion, why should we even attempt to measure the SIJ movement in the diagnosis of PGP?

The Chamberlain x-ray projection has been used to attempt to diagnose SIJ movement, and in paper II, we wanted to determine whether there was movement in the SIJ during the single-leg stance test. We only found minor movement, with total rotation of 0.5° in both the standing leg SIJ and the hanging leg SIJ. Researchers have used this method to establish a relationship between movement detected in the pubic symphysis and pain in the SIJ (Anderson and Peterson 1944, Chamberlain 1930, Mens et al. 1999, Siegel et al. 2008), but the findings have not been uniform. Hence, based on the results of paper II, the Chamberlain examination was likely inadequate for examining SIJ movement in patients with PGP. Furthermore, there did not seem to be any difference between symptomatic and asymptomatic SJs. Based on the range of motion being limited and the measuring methods lacking proper precision, it does not seem valid to measure SIJ movement in clinical practice.

If the range of movement in the SIJ is limited, why would SIJ fusion help these patients?

As described in the European guidelines, the stability of the SIJ is more a matter of altered laxity or stiffness than an increased range of motion (Vleeming et al. 2008). Using Doppler imaging and small vibrations made by a vibrating device, authors have been able to measure laxity (Damen et al. 2002a, Damen et al. 2002c). During pregnancy, increased laxity of the SIJ has been reported, but the values returned to pre-pregnancy status within 8 weeks (Damen et al. 2002a). In this study, the authors found that asymmetrical laxity during pregnancy was associated with increased pain post-partum, but the magnitude of the laxity was not important. In another paper, the same authors demonstrated that a pelvic belt reduced laxity (Damen et al. 2002b), and a pelvic belt was also shown to increase the functional abilities of patients with PGP because the ASLR improved with a pelvic belt (Mens et al. 1999). Sturesson et al. (1999) demonstrated that the movement was reduced by 50% when a pelvic frame was applied to the pelvis. The use of an external frame has been reported to reduce pain in patients with PGP (Slatis and Eskola 1989). Hence, pelvic mobility could be more a matter of laxity within a small range of motion, and because a stabilizer such as a pelvic belt or frame can reduce symptoms, SIJ fusion might be an appropriate treatment option in some severe cases (Sturesson et al. 1999).

The SIJ as a pain generator

The SIJ has neural structures in the joint and in the surrounding ligaments, and these structures can be stressed, with pain as a consequence. However, there have been many theories and models created to explain the underlying causes of PGP.
and SIJ pain. It has been emphasized that the disorder of PGP must be viewed in a bio-psycho-social framework because many factors are important when treating a patient with a long-term pain syndrome (O’ Sullivan and Beales 2007).

In our studies, we primarily examined the bio-mechanical properties of the SIJ. Sacroiliac fusion immobilized the SIJ, and the effects could be observed as a direct consequence of increased stabilization of the pelvic joints. With this approach to the problem, the premise was that the SIJ was the major pain generator. According to the results of SIJ injections in patients with PGP, as well as in patients with non-specific LBP, this premise could be true (Simopoulos et al. 2012). With a single injection and with a cut-off of between 50% and 80% pain relief, an average prevalence of 30–35% was observed, and a higher cut-off (>80%) yielded a slightly lower prevalence (Simopoulos et al. 2012). With a dual block (confirmatory blocks), the prevalence was estimated to be 25%, but with a wide range of 10–40%. When SIJ injections have been used as a “gold standard”, the prevalence has varied because the “gold standard” is not standardized. Furthermore, the patients have often been selected differently, resulting in a prevalence with a broad range. Schwarzer et al. (1995) studied 100 patients with low back pain, and after screening (pain below L5–S1 and over the SIJ), 43 patients were assigned to SIJ injections due to suspected SIJ pain. Thirteen of 43 experienced positive effects from the injections (more than 75% relief), representing a 30% prevalence in patients with suspected SIJ pain, but in the entire sample of LBP patients, the prevalence was 13%. Hence, in a selected population, the prevalence became greater. Using injections only, Laplante et al. (2012) found a 18% prevalence of SIJ pain in 153 cases of patients with non-specific LBP, and interestingly, the prevalence in a population of 54 patients with suspected SIJ pain was 19% (Maigne et al. 1996). The highest prevalence reported was 62% in a highly selected group of patients (Slipman et al. 1998). These patients had 3 positive SIJ provocation tests, and they were assigned to a rehabilitation program. Those who failed this program received diagnostic SIJ injections. Thirty-one of 50 had positive responses to the injections, yielding a prevalence in this population of 62%. Based on these investigations, it seems that the SIJ could be a source of pain in a large proportion of patients with suspected PGP, as well as in patients with non-specific LBP.

Some researchers have proposed that the pain is caused by subluxation or displacement of the SIJ, and the treatment has thus primarily been based on manipulation to correct this (O’Sullivan and Beales 2007). Positive short-term effects of this treatment have been reported (Wright 1995), but the effects did not seem to last. Although these manipulations have effects on the symptoms, the position of the SIJ does not seem to be altered during these treatments (Tullberg et al. 1998). Hence, subluxation of the joint as a reason for PGP seemed not to be correct.

Disturbances in the motor control of the lumbo-pelvic musculature has been emphasized as a possible cause of PGP because this impairment alters the ability to transfer load through the pelvis and triggers nociceptive structures (O’Sullivan and Beales 2007). A treatment program focusing on training in motor control has been shown to have statistically and clinically significant and long-lasting effects on PGP post-partum (Stuge et al. 2004a, Stuge et al. 2004b), but some patients did not respond to this treatment. Different patterns of motor control impairments could explain these findings, and PGP has been associated with both excessive and insufficient motor activation of the pelvic musculature (O’ Sullivan and Beales 2007). It has been suggested that over-activity of the pelvic floor muscles might reduce force closure by counter-nutation in the SIJ, and it could be a possible mechanism for maintaining pain and disability in patients with PGP (Pool-Goudzwaard et al. 2004). Stuge et al. (2012, 2013) found that women with PGP had a statistically significantly smaller levator hiatus, even at rest, and a tendency for higher vaginal resting pressure might indicate increased activity of the pelvic floor muscles. The reason for this is unknown, but could be a response to SIJ pain. Under pelvic floor muscle contraction, the coccyx moves in a ventral and cranial direction (Bo et al. 2001), and it most likely generates counter-nutation in the SIJ (Pool-Goudzwaard et al. 2004). Because counter-nutation might lead to increased tension in the ligamentous structures (Snijders et al. 1993), sustained contraction of the pelvic floor muscles might be a non-optimal strategy, leading to stress on the ligaments and resulting in pain. Palssson and Graven-Nielsen (2012) recently showed that superficial ligament structures were potential pain sources in PGP (Palssson and Graven-Nielsen 2012, Stuge et al. 2012, Stuge et al. 2013).

Another group receiving increasing interest is patients with failed back surgery. In patients with persistent pain after spinal fusion, Depalma et al. (2011) used SIJ injections and found the SIJ was the source of pain in 43%, and 83% of these patients had fusion to the sacrum. These findings were similar to those of another study that found 35% positive blocks in patients with pain after spinal fusion (Maigne and Planchon 2005). Increased SIJ degeneration was found, compared to un-operated subjects, 5 years after spinal fusion, particularly in cases with lumbosacral fusion (Ha et al. 2008). Patients with a suspected SIJ origin of pain after spinal fusion also reported a different type of pain than that for which they primarily underwent surgery (Maigne and Planchon 2005). The importance of SIJ degeneration in patients with suspected SIJ pain is not fully understood because degenerative changes have been observed in both asymptomatic and symptomatic patients (Elgafy et al. 2001). However, with the use of finite element analysis, increased stress in the SIJ has been reported, particularly if there was a sacro-lumbar fusion (Ivanov et al. 2009), and increased tension on the SIJ structures can possibly cause pain. Based on these studies, the SIJ could be a pain generator in patients with failed back surgery; furthermore, these patients have reported responding positively to SIJ fusion (Rudolf 2013).
Surgery as a treatment for PGP

In paper III, we found a mean 17-point decrease in the ODI (from 54 to 37) and a mean 25-point decrease in the VAS (from 82 to 57) one year after SIJ fusion was performed. Pre-operatively, these patients had a high degree of disability and high levels of pain. One patient did not experience any effects from the intervention, but the remainder had significant decreases in ODI and VAS scores. The minimal clinically significant difference has been suggested to be 10 points in the ODI (Hagg et al. 2003), and in our study, 7 of 8 patients achieved this difference. For the VAS, the minimal clinically significant difference has been suggested to be 18 (Hagg et al. 2003). Six of 8 patients had a change of 18 or greater on the VAS; one had a 16-point change, and one had a small change of only 3. As a group, the patients experienced positive effects from surgery, and the changes seemed to be of statistical and clinical significance.

In the long-term follow-up (reported in paper IV), the patients had a mean ODI score of 33 (95% CI: 24–42) and a mean VAS score of 54 (95% CI: 46–63), comparable to the 1-year results reported in paper III. Compared to a comparable non-surgery group, the operated patients in the long-term follow-up had lower ODI (33 compared to 37) and VAS scores (54 compared to 60), but these differences were not statistically significant. There are possible explanations for this lack of difference. The most tempting interpretation to make of this finding is that SIJ fusion had no effects, but the study was not designed to draw such a conclusion. The nonsurgery group differed from the surgery group with regard to age and length of follow-up. The non-surgery group was diagnosed with severe PGP by the same surgeon, but the patients in that group were likely less disabled at baseline than the group of patients who underwent surgery; hence, the comparison might have had limited validity. What was discovered, however, was that the patients with successful short-term results had significantly better outcomes than the patients with poor short-term results, and the short-term results were correlated with both the ODI and VAS over the long-term follow-up. The studies in both paper III and paper IV had specific selections of patients, and with the use of the inclusion criteria described in paper III, it seems that positive effects from surgery could be expected.

In our study (paper III), there was clinical improvement, but the patients continued to have moderate disability and relatively high pain scores after 1 year, and one patient did not experience any effects at all. One explanation for this finding is the limitation of the use of outcomes. Most of the patients had bilateral SIJ pain at inclusion (7 of 8), but only the most painful joint and the symphysis were fused. Because the outcome measures tested the overall pain and functioning of the patients, the non-fused joints influenced the measured values of the ODI, VAS and SF-36. In paper III, 6 of 8 patients were pain-free in the fused joint, but six of seven reported pain on the contralateral side, which could indicate that the function and pain could have been further improved if the patients had undergone fusion of the other joint as well.

How do our results compare to those of other studies?

When the literature was explored, only 28 original papers and 2 book chapters were found (Appendix 1), and most of the older papers did not include any validated outcome measures. There were only case series without control groups. The patient selection and surgical techniques also differed in almost every paper, and no studies reported the outcomes of our surgical method. Hence, a comparison of our results to others is difficult, but there have been several studies that have reported the outcomes of SIJ fusion using similar inclusion criteria. A positive effect of surgery has been observed in 50% to 90% of patients (Appendix), and this finding is in accord with the positive effects observed in our 1-year outcomes. In a prospective study of 58 patients, van Zwienen et al. (2004) reported a mean increase in physical outcomes from 37 to 61 (p < 0.001) as measured using the Majeed score (0 – poor, 100 – good), and the same positive results have been reported in several papers (Appendix, Table 7).

Although positive results have been reported, a number of patients have not experienced effects from surgery. In our long-term study, 28% of patients did not experience any effects from surgery, and these findings were comparable to those of other studies (van Zwienen et al. 2004, Buchowski et al. 2005, Wise and Dall 2008, Rudolf 2012, Duhon et al. 2013, Smith et al. 2013). Most of these patients had complications or non-union events, but some experienced no effects without any clear explanation. Open surgery causes extensive surgical trauma, and some of these patients may have experienced pain due to soft tissue trauma caused by surgical exposure. It has been shown that 10–15% of patients develop chronic pain after simple iliac crest bone harvesting (Laurie et al. 1984, Delawi et al. 2007), which is a similar, but much smaller, procedure to open SIJ fusion. In our study, one patient did not experience any effects from the surgery. This patient had a more generalized pain pattern than the others and it is possible that the SIJ was not the major source of pain in this case, although this patient had a positive response to the SIJ injection. In contrast, the patients who reported sharp and localized pain in the SIJ area did benefit from surgery. It has been reported that the outcomes improved if patients with psychosomatic disorders were excluded, with the success rate increasing from 50% to 70% (Waisbrod et al. 1987). Because SIJ fusion has effects in many patients with PGP, the SIJ or the surrounding ligaments could be the origin of pain in many of these patients, but in patients with more generalized pain patterns, other pain generators might influence the outcome of surgery. The reason for the effect of SIJ fusion is, however, not known. In theory, SIJ fusion can correct many biological disturbances, but it also has a psychological influence on the patient, including placebo effects.
The placebo effect after surgery has been shown to be an important factor in short-term efficacy (Turner et al. 1994) and particularly in the treatment of chronic pain, in which the psychological component is believed to be an important factor. For example, in a study using sham surgery as much as 43% of the patients in the placebo group had pain relief after sham lumbar discectomies (Spangfort 1972), and other similar sham procedures have also reported to have a significant effect on clinical outcome (Vandana and Tushar 2001). There are several factors in both the patients and examiners that contribute to the placebo effect. Patients with long-lasting diseases seems to be poorer placebo responders, but on the other hand placebo tend to work better in patients expecting to have changes in sensation of pain (Vandana and Tushar 2001). Our patients was included according to specific criteria and might feel a special need to become pain free, and this can enhance the placebo effect. They also got a relationship with the examiners because we used multiple testing. Hence, some of the positive effect of SIJ fusion seen in paper III can of course be placebo. In our long-term study (paper IV), almost three-quarters of the patients reported to be relieved, or almost relieved, from pain after 1 year, and 28% were not. The 1-year results for the operated patients seemed to be sustained throughout life because patients with successful 1-year results had both significantly less pain and less disability than the patients with unsuccessful 1-year results. With these results, it is difficult to believe that the placebo effect is the only contributor to successful surgical outcomes.

**Future of SIJ fusions**

It has been questioned whether MIS implants can improve the outcomes of SIJ fusion. Over the last decade, minimally invasive procedures have been introduced, and the use of implants has become popular. Between 2009 and 2013, more than 5000 patients were treated with a specific implant (Miller et al. 2013). In the last few years, several manufacturers have created MIS implants for use in SIJ fusion, but studies have been published for only three of these implants. In 2008 and 2009, two papers were published regarding the use of a traditional, hollow, cylindrical screw across the SIJ (Al-Khayer et al. 2008, Khurana et al. 2009). To achieve fusion, the study authors filled the screw with BMP-2 or demineralized bone matrix. They reported the outcomes of 24 patients with suspected SIJ pain; the fusion rate was 100%, and the clinical outcomes were promising (Table 7). Later, Mason et al. (Mason et al. 2013) reported the outcomes of 55 patients using the same technique and reported no implant failures, two cases of nerve damage and no other complications. Although the complication rate was lower, the clinical outcomes were not better than those of our study (paper III) in which open anterior surgery was performed (Table 7).

Recently, two other MIS techniques have been developed: the iFuse implant (SI-bone Inc., San Jose, CA, USA) and the Distraction Interference Arthrodesis Neurovascular Anticipating (DIANA) implant (Signus Medizintechnik, Alzenau, Germany). Outcomes with the iFuse implant have been reported in 5 studies (Table 7), and the complication rate has been reported to be between 0% and 20%. The implant is a triangular, coated implant that is applied across the SIJ, and the SIJ is indirectly fused as the bone grows into the implant. The implant seems promising with regard to clinical outcomes and complication rates, and it has been reported to be cost-effective in the treatment of SIJ pain (Ackerman et al. 2013). In a retrospective, multi-center study of 263 patients, the implant showed better clinical outcomes than open surgery (3.5 points lower on a VAS at 12 months in the MIS group), fewer complications and a shorter hospitalization time (Smith et al. 2013). Unfortunately, the authors of these studies have close connections to the corporation that produces these products (SI-bone) as consultants, stockholders or employees of the company, and the company has sponsored some of the studies. Hence, these results should be interpreted with caution and replicated by independent researchers. The DIANA is another type of titanium implant that is inserted dorsally into the recess. Only one original paper with 19 patients has been published, with a fair

**Table 7. Outcome of studies using ODI or/and VAS/NRS as outcome measures**

| Authors   | VAS     | ODI     | Preop | Postop | Change | Δ (%) | Preop | Postop | Change | Δ (%) |
|-----------|---------|---------|-------|--------|--------|-------|-------|--------|--------|-------|
| Al-Khayer 2008 | 8.1     | 8.5     | 4.6   | 3.5    | 43     | 59    | 45    | 14     | 24     |
| Mason 2013    | 8.0     | 7.5     | 4.5   | 3.5    | 44     | 55    | 39    | 16     | 29     |
| Sachs 2012    | 7.9     | 6.9     | 2.3   | 1.6    | 51     | 55    | 39    | 16     | 29     |
| Rudolf 2012   | 7.6     | 6.1     | 3.3   | 2.4    | 57     | 55    | 39    | 16     | 29     |
| Sachs 2013    | 8.7     | 6.8     | 0.9   | 0.8    | 71     | 55    | 39    | 16     | 29     |
| Cunnings 2013 | 8.9     | 8.2     | 2.3   | 1.6    | 74     | 55    | 39    | 16     | 29     |
| Duhun 2013    | 7.6     | 6.8     | 2.9   | 1.6    | 62     | 55    | 39    | 16     | 29     |
| Endres 2013   | 8.6     | 6.5     | 6.0   | 4.5    | 29     | 55    | 39    | 16     | 29     |
| Kibsgård 2014 | 8.2     | 6.6     | 5.7   | 4.1    | 30     | 55    | 39    | 16     | 29     |
| Mean         | 8.2     | 6.8     | 3.6   | 2.4    | 56     | 55    | 39    | 16     | 29     |

All studies used MIS to achieve SIJ fusion. Implants used in the studies: a hollow cylindrical screw, b iFuse, and c DIANA.
fusion rate and no infections or no nerve damage. The clinical outcomes, in contrast, were worse than our results (Table 7), with a decrease in the ODI from 64 to 57 and a reduction in the VAS from 85 to 60.

In conclusion, the new MIS implants seem safer than open access surgery, with low reported complication rates. The surgical trauma is far less when using MIS, and consequently, the length of the hospital stay is shorter. The clinical outcomes have been reported to be as good, or even better, than the old open technique. However, more studies have to be performed; the studies must be of higher quality; and importantly, the studies must be performed independently of industry. Additionally, future studies should focus on optimal inclusion criteria for SIJ fusion.
Conclusions

This thesis showed the following:

- Radiostereometric analysis applied to the SIJ has high accuracy and precision and is suitable as a tool for investigating SIJ movement. In patients, more than 4 markers in each segment are recommended to ensure obtaining a proper segment to use in the analysis. The use of frontal markers does not improve the precision and is therefore unnecessary.

- In patients with PgP, the movements in the SIJ in the single-leg stance are small and almost undetectable by the precise RSA method. We measured a mean rotation of 0.5° in both the standing- and hanging-leg SIJs, and no translation was detected. There were no differences in total movement between the standing- and hanging-leg SIJs. The interpretation of the results of this study is that the Chamberlain examination is likely inadequate for examining SIJ movement in patients with PGP.

- One year after open unilateral anterior SIJ fusion combined with symphysis pubis fusion, positive and significant changes were observed in both physical function and pain. Despite these positive results, this procedure was associated with adverse events and complications.

- Patients with chronic PGP who underwent SIJ fusion reported being moderately disabled, with moderate or severe pain intensity, 23 years after surgery. Approximately half of these patients had successful 1-year outcomes, and in these patients, their good results were sustained 23 years after surgery. Two-thirds of the patients experienced positive long-term effects from fusion surgery, and 20% reported no effects from the surgery.
Summary

The sacroiliac joint (SIJ) might be the source of pain for 13-30% of patients with low back pain and possibly an even greater proportion of patients suffering from “failed back surgery”. This pain can be caused by specific pathology of the joint, but the specific role of the SIJ in unspecific pelvic girdle pain (PGP) disorder remains unknown. PGP is a common complaint in pregnancy that can cause disability, and in some women, the complaint continues after delivery. The origin and diagnosis of PGP are also unclear because radiological findings are often absent, and the diagnostic criteria lack sufficient evidence. However, it has become increasingly apparent that patients with PGP have different clinical presentations than patients suffering from low back pain. Based on the theory of pathological joint mobility, SIJ fusion combined with symphysis pubis fusion is a therapeutic option when conservative treatment has been unsuccessful.

This thesis includes four papers. In the first two papers, we used a specialized x-ray method, called radiostereometric analysis (RSA), to evaluate the movement of the SIJ, and in the last two papers, we evaluated the outcomes after SIJ fusion.

In paper I, we evaluated the RSA method when this method was applied to the SIJ. We used a phantom model to measure the true values of movements, and these values were compared to the measurements obtained by RSA imaging. By this process, we could determine whether there was any bias that had to be corrected for when this method was used. Furthermore, we measured the precision of the method in the phantom model and in patients. The main results were that the accuracy and precision of the RSA method were high, and the method could be used to measure SIJ movement.

In paper II, we used the RSA method to measure the movement in the SIJ in the single-leg stance. Chamberlain described a method for indirectly measuring SIJ movement by measuring the movement in the pubic symphysis on anterior-posterior (A-P) x-rays. This procedure was performed in the single-leg stance, and Chamberlain attempted to correlate the pubic movement with SIJ pain. However, there have been different reports regarding this relationship, which have made it difficult for clinicians to use the results of the Chamberlain test in the diagnosis of PGP, particularly when normal variations in the movement of the pubic symphysis have also proven to be large. We used RSA to measure the movement in the SIJ in the single-leg stance in 11 patients, and the movements were small and almost undetectable using the method. We measured a mean rotation of 0.5° on both the standing-and hanging-leg SIJs, and no translation was detected. There were no differences in total movement between the standing- and hanging-leg SIJs. From the results of this study, we consider the Chamberlain examination to likely be inadequate for evaluation of SIJ movement in patients with PGP.

In paper III, we used a single-subject design study to evaluate the outcomes of pain, disability and health-related quality of life 1 year after SIJ fusion in 8 patients with severe PGP. These patients were included by applying strict inclusion and exclusion criteria, and they were submitted to surgery with anterior unilateral SIJ fusion combined with a fusion to the pubic symphysis. One year after open unilateral anterior SIJ fusion combined with symphysis pubis fusion, positive and significant changes in both physical function and pain were observed. Despite these positive results, this procedure was associated with adverse events and complications.

In the last paper, paper IV, we performed a long-term follow-up of 50 patients who underwent SIJ fusion performed by Sudmann in Haggvik, Bergen, Norway. All of the patients completed a questionnaire that measured the outcomes of pain, disability and health-related quality of life, and these outcomes were compared with the 1-year outcomes collected by the Sudmann. A comparison group of 28 patients who did not receive SIJ fusion completed the same questionnaire. Patients with chronic PGP who underwent SIJ fusion reported being moderately disabled, with moderate or severe pain intensity 23 years after surgery. Approximately half of these patients had successful 1-year outcomes, and in these patients, good results were sustained 23 years after surgery. Two-thirds of the patients experienced a positive long-term effect from fusion surgery, and 20% reported no effects from the surgery. It appeared that this surgery was an appropriate treatment option for a select group of patients with severe PGP, but which patients would benefit from surgery remains unclear.
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### Appendix

#### Table. Former studies reporting surgical outcomes after sacroiliac joint fusion

| Author/year | N  | P/R | Surgical method | Fusion rate | Functional outcome | Result |
|-------------|----|-----|-----------------|-------------|--------------------|--------|
| Smith-Petersen 1921 | 13 | R   | Trans-iliac-window (Smith-Petersen) | NA          | Authors opinion    | Uniformly successful |
| Smith-Petersen and Rogers 1926 | 26 | R   | Smith-Petersen | 95% on x-ray | Recovery – absolute relief | Complete recovery 86% Failures 8% |
| Gaenslen 1927 | 9  | R   | Smith-Petersen | NA          | Very good          | 3 very good |
| Millner and Lowendorf 1931 | 12 | R   | Smith-Petersen | NA          | Good Failure       | 4 good |
| Mitchell 1938 | 15 | R   | 3 Smith-Petersen Campbell | NA          | Good Poor          | 10 good 2 fair |
| Avilia 1941 | 4  | R   | 3 Antero-lateral 1 Smith-Petersen 2 Pubic symphysis only | 6/8         | Good Poor Residual pain | 6 good 1 fair 4/8 SIJ pain |
| Hagen 1974 | 8  | R   | Smith-Petersen | 100% SIJ NA 20 (90%) | Satisfactory Unsatisfactory 50% pain relief | Complete relief 50% satisfactory 50% unsatisfactory 70% satisfactory without psychosomatic patients |
| Rand 1985 | 1  | R   | Anterior fusion Dorsal resection, bone graft | NA          | –                  | – |
| Waisbrod et al. 1987 | 22 | R   | Dorsal resection, 20 (90%) | 100% PS 5 SIJ fusion | SIJ fusion No fusion was performed | 49/58 (84%) |
| Lippitt 199 | 15 | R   | SI screws No fusion 1 loosening | –           | Classified by surgeon 11 excellent 1 re-operations 3 minor | – |
| Keating et al. 1997 | 39 | P   | Debridement and screw | –           | Pain level VAS Male Female 4.4–2.4 5.8–2.7 | – |
| Güner 1998 | 1  | R   | Endoscopic anterior fusion Dorsal resection + pedicle screw | 100% 100% | Self-reported satisfaction | 4/5, 1 degenerative spine |
| Belanger and Dall 2001 | 4  | R   | Sacroiliac bone plugs | 100% PS 49/58 (84%) | Complete relief Majeed | 37–69 |
| Giannikas et al. 2004 | 5  | P   | Plating PS Bilateral SI screws 17/20 (85%) | –           | SF-36 Physical sum Mental sum | – |
| van Zwienen et al. 2004 | 58 | P   | Modified Smith-Petersen Plate-screws | 100% SI screws and ilium connecting bolt | Questionable fusion 4 Non-union 7 Fusion 6 | – |
| Buchowski et al. 2005 | 20 | P   | Bilateral SIJ fusion with SI screws and ilium to ilium connecting bolt | Questionable fusion 4 Non-union 7 Fusion 6 | VAS | – |
| Schutz and Grob 2006 | 17 | P   | Bilateral SIJ fusion with SI screws and ilium connecting bolt | Questionable fusion 4 Non-union 7 Fusion 6 | VAS | – |
| Ziran et al. 2007 | 17 | P   | SI screws CT guided | No fusion was performed | VAS | – |
| Wise and Dall 2008 | 13 | P   | MIS - threaded fusion cage BMP-2 17/19 joints (89%) | LBP VAS score | – | – |
| Al-Khayer et al. 2008 | 9  | P   | Hollow cylindrical screw | ODI | VAS | – |
| Khurana et al. 2009 | 15 | P   | Hollow cylindrical screw Demineralized bone matrix | 100% fusion | SF-36 Physical sum Mental sum Majeed | – |

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*Note: N refers to the number of patients, P is percutaneous, and R is open.*
| Author/year                        | N  | P/R | Surgical method          | Fusion rate | Functional outcome | Result                                                                 |
|-----------------------------------|----|-----|--------------------------|-------------|--------------------|------------------------------------------------------------------------|
| Stark et al. 2011)                | 75 | P   | Diana                    | 92% fusion  | Million VAS        | Improvement in total score (p < 0.0001) 28/41 work candidates         |
| Sachs and Capobianco 2012         | 11 | P   | iFuse                    | No revision | Return to work VAS | Pre–post: 7.9–2.3, 80% over 2 point on VAS                            |
| Rudolf 2013                       | 50 | P   | iFuse                    | 20% compli-| NRS pain           | Pre–post: 7.6–3.3, 20% partly satisfied                               |
|                                   |    |     | cation 95% ingrowth after 6 months |              |                    |                                                                         |
| Mason et al. 2013                 | 55 | P   | Hollow modular screw     | NA          | VAS                | Pre – 1 year: 8.0–4.5                                                 |
|                                   |    |     | Demineralized bone matrix| No late failures | Majeed VAS | Pre – 1 year: 8.7–0.9, 1 failure                                     |
|                                   |    |     | iFuse                    | No revisions |                    |                                                                         |
| Cummings and Capobianco 2013      | 18 | P   | iFuse                    | VAS         |                    | Pre – 1 year: 8.9–2.3                                                 |
|                                   |    |     |                          | ODI         |                    | Pre – 1 year: 53–13                                                   |
|                                   |    |     |                          | VAS         |                    | Pre – 6 months: 7.6–2.9                                               |
| Duhon et al. 2013                 | 32 | P   | iFuse                    | VAS         |                    | Pre – 6 months: 55–39                                                  |
|                                   |    |     |                          | ODI         |                    | Pre – 13.2 m: 8.5–6.0                                                  |
| Endres and Ludwig 2013            | 19 | P   | DIANA                    | 79% fusion  | VAS                | Pre – 13.2 m: 64–57                                                   |
| Total                             | 631|     | 18 different techniques | Fusion rate | ODI                |                                                                         |
|                                   |    |     |                          | 24–100%     |                    |                                                                         |

a P – prospective, R – Retrospective.
