

# Changes in rates of arthroscopy due to degenerative knee disease and traumatic meniscal tears in Finland and Sweden

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**Background and purpose** — Knee arthroscopy is commonly performed to treat degenerative knee disease symptoms and traumatic meniscal tears. We evaluated whether the recent high-quality randomized control trials not favoring arthroscopic surgery for degenerative knee disease affected the procedure incidence and trends in Finland and Sweden.

**Patients and methods** — We conducted a bi-national registry-based study including all adult (aged  $\geq 18$  years) inpatient and outpatient arthroscopic surgeries performed for degenerative knee disease (osteoarthritis (OA) and degenerative meniscal tears) and traumatic meniscal tears in Finland between 1997 and 2012, and in Sweden between 2001 and 2012.

**Results** — In Finland, the annual number of operations was 16,389 in 1997, reached 20,432 in 2007, and declined to 15,018 in 2012. In Sweden, the number of operations was 9,944 in 2001, reached 11,711 in 2008, and declined to 8,114 in 2012. The knee arthroscopy incidence for OA was 124 per  $10^5$  person-years in 2012 in Finland and it was 51 in Sweden. The incidence of knee arthroscopies for meniscal tears coded as traumatic steadily increased in Finland from 64 per  $10^5$  person-years in 1997 to 97 per  $10^5$  person-years in 2012, but not in Sweden.

**Interpretation** — The incidence of arthroscopies for degenerative knee disease declined after 2008 in both countries. Remarkably, the incidence of arthroscopy for degenerative knee disease and traumatic meniscal tears is 2 to 4 times higher in Finland than in Sweden. Efficient implementation of new high-quality evidence in clinical practice could reduce the number of ineffective surgeries.

ing to knee osteoarthritis (OA). Nonoperative treatment of degenerative knee disease is recommended in guidelines, but arthroscopy is widely used (Kim et al. 2011, Nelson et al. 2014). Arthroscopic treatment includes debridement (lavage, smoothing, and removal of loose articular cartilage fragments), treatment of cartilage lesions, and resection of meniscal lesions (Felson 2010). Meniscal repair is preferred for acute traumatic tears of the meniscus (Sgaglione 2005). However, it is often difficult to distinguish between degenerative and traumatic meniscal tears. In older individuals and in patients with knee OA, meniscal tears are often degenerative and their prevalence increases with age (Curl et al. 1997, Metcalf and Barrett 2004, Englund et al. 2008). In younger patients, traumatic meniscal tears usually result from acute knee injury and are often associated with tears of the anterior cruciate ligament (Poehling et al. 1990).

The practice of knee arthroscopy is in turmoil. In 2002, a pivotal randomized and placebo- (surgery) controlled trial found that arthroscopic debridement or lavage is no better than a sham procedure for treating knee OA (Moseley et al. 2002). This finding was later corroborated by Kirkley et al. (2008). This evidence led to recommendations to avoid knee arthroscopy procedures for patients with a primary diagnosis of knee OA (Conaghan et al. 2008, Richmond et al. 2009, Zhang et al. 2010). The recommendations, however, provided the option of knee arthroscopy in patients with signs and symptoms of a torn meniscus (Conaghan et al. 2008, Richmond et al. 2009) and for patients with low-grade OA (Zhang et al. 2010).

Previous reports regarding the trends in a number of knee arthroscopic procedures indicate a reduced incidence of arthroscopies for knee OA, and a steady increase in the number of arthroscopic meniscus surgeries (Hawker et al. 2008, Kim et al. 2011, Abrams et al. 2013). In the UK, the incidence of

Degenerative knee disease produces a variety of symptoms, clinical findings, and tissue abnormalities, eventually lead-

Table 1. ICD-10 diagnosis and NCSP procedural codes included in Finland and in Sweden

ICD-10 diagnoses	Procedural codes in Finnish coding system (Lehtonen et al. THL 2013)	Procedural codes in Swedish coding system (Socialstyrelsen 2004)
<b>Osteoarthritis</b>		
M17.0 Primary gonarthrosis, bilateral	NGA30 Arthroscopic exploration of knee joint	NGA11 Arthroscopic exploration of knee joint
M17.1 Gonarthrosis, bilateral	NGD05 Arthroscopic partial resection of menisci	NGD11 Arthroscopic partial resection of menisci
M17.3 Other post-traumatic gonarthrosis	NGF25 Arthroscopic debridement of knee joint	NGF31 Arthroscopic debridement of knee joint
M17.9 Gonarthrosis, unspecified	NGF35 Arthroscopic partial excision of joint cartilage of knee	NGF91 Partial excision of joint cartilage of knee
M22.4 Chondromalacia patellae		
<b>Degenerative meniscal tear</b>		
M23.2 Derangement of meniscus due to old tear or injury	NGA30 Arthroscopic exploration of knee joint	NGA11 Arthroscopic exploration of knee joint
M23.3 Other meniscal derangements	NGD05 Arthroscopic partial resection of menisci	NGD11 Arthroscopic partial resection of menisci
M23.4 Loose body in knee	NGF25 Arthroscopic debridement of knee joint	NGF31 Arthroscopic debridement of knee joint
M23.8 Other internal derangements of knee	NGF35 Arthroscopic partial excision of joint cartilage of knee	NGF91 Partial excision of joint cartilage of knee
M23.9 Internal derangement of knee, unspecified		
<b>Traumatic meniscal tear, debridement</b>		
S83.2 Tear of meniscus, current	NGA30 Arthroscopic exploration of knee joint NGD05 Arthroscopic partial resection of menisci NGF25 Arthroscopic debridement of knee joint NGF35 Arthroscopic partial excision of joint cartilage of knee	NGA11 Arthroscopic exploration of knee joint NGD11 Arthroscopic partial resection of menisci NGF31 Arthroscopic debridement of knee joint NGF91 Partial excision of joint cartilage of knee
<b>Traumatic meniscal tear, repair</b>		
S83.2 Tear of meniscus, current	NDG25 re-insertion of meniscus	NGD21 re-insertion of meniscus

arthroscopic meniscal resections more than doubled from 2000 to 2012 in patients over 60 years of age (Lazic et al. 2014). Similarly, in Denmark the number of meniscal procedures in patients aged 35 years or more increased during the period 2000–2011 (Thorlund et al. 2014).

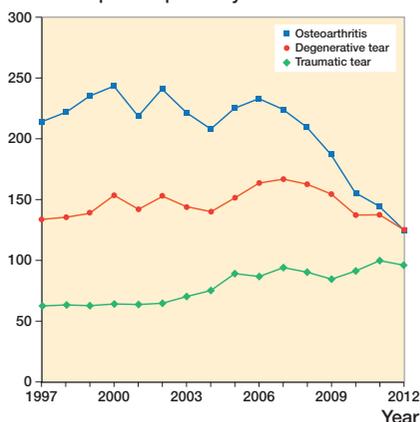
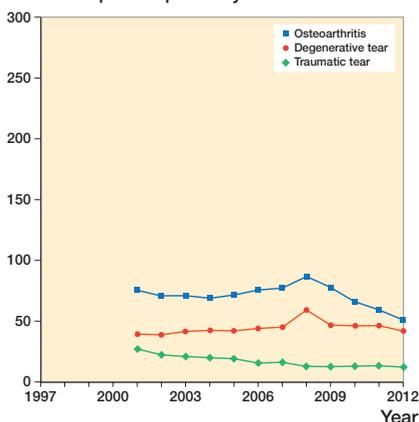
In this bi-national registry-based study involving the entire populations of Finland and Sweden, we assessed the numbers and incidence trends of arthroscopic knee procedures for degenerative knee disease and meniscal tears in Finland (between 1997 and 2012) and in Sweden (between 2001 and 2012).

## Patients and methods

We used the Finnish and Swedish National Hospital Discharge Registers (NHDRs) to evaluate the incidence of and trends in arthroscopic surgery for degenerative knee disease and meniscal tears. All patients 18 years of age or older in both NHDRs were included. In Finland, data were available from January 1, 1997 through December 31, 2012, and in Sweden, data were available from January 1, 2001 through December 31, 2012. The Finnish and Swedish NHDRs provide excellent databases for epidemiological studies, as they contain data on age, sex, and domicile of the subject; length of hospital stay; primary and secondary diagnoses; and operations performed during the hospital stay. The data collected by the NHDR are mandatory for all hospitals to provide—including private, public, and other institutions—for both inpatient and outpatient settings. Although coverage and accuracy of both NHDRs is good (Ludvigsson et al. 2011, Sund 2012, Huttunen et al.

2014), an internal validity control of the data revealed that 2 hospitals in Stockholm, Sweden had performed approximately 1,800 knee arthroscopies annually for degenerative knee disease or meniscal tears in recent years, whereas the number had doubled in 2012, raising suspicion of double-coding of procedures (Socialstyrelsen 2009, Socialstyrelsen 2014). Thus, due to the potential problems with internal validity, we excluded these 2 hospitals in Stockholm from the analysis with regard to the whole study period (2001–2012).

The main outcome variable was the number of knee arthroscopies performed for degenerative knee disease (including OA and degenerative meniscal tears) and traumatic meniscal tears (Table 1). For diagnoses, the ICD-10 coding system was used, and for procedural coding, we used the national NCSP procedural codes maintained by NOMESCO (Socialstyrelsen 2004, Lehtonen et al. THL 2013). These coding systems allow physicians to set multiple diagnoses. We categorized knee arthroscopies based on the diagnosis and procedural codes as follows: (a) Osteoarthritis, (b) Degenerative meniscal tear, (c) Traumatic meniscal tear undergoing debridement/resection, and (d) Traumatic meniscal tear undergoing repair (Table 1). The code M23\* (meniscal derangement due to old tear or injury or other meniscal derangements) was used for degenerative meniscal tears, and the code S83.2 (acute meniscal tear) was used for traumatic tears. In cases of multiple knee diagnoses for the same surgical procedure (e.g. a first diagnosis of M23\* and a second of M17\*, or a first diagnosis of M23\* and a second of S83.2), the procedure was categorized according to the more degenerative diagnosis (e.g. M17 and M23 was defined as M17, and M23 and S83 as M23).

Incidence per 10<sup>5</sup> person-years – FinlandIncidence per 10<sup>5</sup> person-years – Sweden

Incidence of knee arthroscopy for osteoarthritis, degenerative meniscal tears, and traumatic meniscal tears in Finland from 1997 to 2012 (left panel) and in Sweden from 2001 to 2012 (right panel), per 10<sup>5</sup> person-years. 2 hospitals in Sweden were excluded due to suspected double-coding.

## Statistics

To compute the incidence of knee arthroscopy, the age- and sex-specific annual mid-population was obtained from the Finnish and Swedish Official Statistics, which yield data from an electronic national population registry (Official Statistics of Finland 2015, Statistics Sweden 2015). The incidence of knee arthroscopy (per 10<sup>5</sup> person-years) was based on the results of the entire adult population ( $\geq 18$  years) of Finland and Sweden rather than cohort- or sample-based estimates, and therefore confidence intervals were not calculated. Statistical analysis was performed using SPSS version 21.0.

## Ethics

We obtained the approval of the Institutional Review Boards of Finland (entry no. THL 89/5.0500/2012) and Sweden (The Regional Ethics Committee of Stockholm, entry no. 2013/5:6).

## Results

During the study period in Finland, from 1997 through 2012, a total of 287,225 knee arthroscopies to treat degenerative knee disease ( $n = 233,375$ ) or traumatic meniscal tears ( $n = 53,850$ ) were identified in the adult population (4.0–4.3 million). The total number of knee arthroscopies for degenerative knee disease or traumatic meniscal tears in 1997 was 16,389, and in 2007 the number peaked to 20,432. Thereafter, the number of arthroscopies declined and was 15,018 in 2012. The mean age of male and female patients was 47 and 52 years, and it did not change markedly during the study period. In Sweden with an adult population of 7.1–7.6 million, the total number of arthroscopies performed for degenerative knee disease or traumatic meniscal tears from 2001 through 2012 was 115,907 (100,469 and 15,438, respectively). The number of operations in 2001 was 9,944, and the highest number of arthroscopies (11,711) was performed in 2008. The number of arthroscopies then declined to 8,114 in 2012 (Figure, Tables 2 and 3). In

general, the incidence rates of knee arthroscopy were markedly lower in Sweden than in Finland.

In Finland, the incidence of knee arthroscopy for OA increased to 240 per 10<sup>5</sup> person-years in 2002 and then decreased by 48% to 124 per 10<sup>5</sup> person-years in 2012. In Sweden, the incidence of knee arthroscopy for OA increased to 87 per 10<sup>5</sup> person-years in 2008, and then decreased by 41% to 51 per 10<sup>5</sup> person-years in 2012. The mean age of OA patients was 54 years in Finland and 52 years in Sweden.

The incidence of arthroscopy for degenerative meniscal tears in Finland increased slightly from 1997 to 2007 (incidence 167 per 10<sup>5</sup> person-years in 2007) and then declined to 125 per 10<sup>5</sup> person-years in 2012. The incidence of arthroscopic debridement for traumatic meniscal tears increased by 55% during the study period from 63 per 10<sup>5</sup> in 1997 to 97 per 10<sup>5</sup> in 2012. In both groups of meniscal tears in Finland, the mean age increased slightly during the study period from 49 years in 1997 to 52 years in 2012 for those with degenerative meniscal tears and from 42 years in 1997 to 46 years in 2012 for those with traumatic meniscal tears undergoing debridement.

In Sweden, the incidence of arthroscopy for degenerative meniscal tears remained practically unaltered (39 to 46 per 10<sup>5</sup> person-years) during the study period, except in 2008 when the incidence was 59 per 10<sup>5</sup> person-years. The mean age of these patients did not change either (46 years in 2001 and 47 years in 2012). The incidence of traumatic tears undergoing debridement decreased during the study period from 27 per 10<sup>5</sup> person-years in 2001 to 13 per 10<sup>5</sup> person-years in 2012. Unlike in Finland, the mean age of patients with traumatic tears undergoing debridement decreased in Sweden during the study period from 39 years in 2001 to 35 years in 2012.

The incidence of meniscal repair for traumatic meniscal tears remained low and unaltered during the study period in both countries, ranging from 2.2 to 1.3 per 10<sup>5</sup> person-years in Finland and from 0.4 to 0.8 per 10<sup>5</sup> person-years in Sweden. The mean age of patients undergoing meniscal repair remained the same during the study period—38 years in Finland and 30 years in Sweden.

Table 2. Incidence of knee arthroscopy (per 10<sup>5</sup> person-years) and mean age of patients for osteoarthritis, degenerative meniscal tear, and traumatic meniscal tear (debridement and repair) in Finland from 1997 to 2012

Year	Osteoarthritis		Degenerative meniscus		Traumatic meniscus (debridement)		Traumatic meniscus (repair)	
	Incidence	Mean age	Incidence	Mean age	Incidence	Mean age	Incidence	Mean age
1997	214	52	134	49	63	42	1.2	44
1998	222	53	136	50	64	42	1.4	40
1999	235	53	139	50	63	43	1.9	39
2000	244	53	154	51	65	43	2.0	43
2001	218	54	142	51	64	43	1.8	37
2002	240	54	153	51	65	43	1.9	38
2003	221	54	144	52	71	44	1.6	39
2004	208	54	140	52	76	44	1.7	41
2005	225	54	151	52	90	45	1.9	39
2006	233	55	164	53	87	45	2.0	39
2007	224	55	167	53	95	45	1.9	42
2008	210	55	163	53	91	45	1.3	38
2009	187	55	155	53	85	45	1.5	40
2010	155	54	138	52	92	46	1.7	38
2011	145	54	138	53	101	46	2.2	37
2012	124	54	125	52	97	46	2.1	40

Table 3. Incidence of knee arthroscopy (per 10<sup>5</sup> person-years) and mean age of patients for osteoarthritis, degenerative meniscal tear, and traumatic meniscal tear (debridement and repair) in Sweden from 2001 to 2012

Year	Osteoarthritis		Degenerative meniscus		Traumatic meniscus (debridement)		Traumatic meniscus (repair)	
	Incidence	Mean age	Incidence	Mean age	Incidence	Mean age	Incidence	Mean age
2001	76	52	40	46	27	39	0.4	28
2002	71	52	39	47	22	39	0.4	30
2003	71	51	41	46	21	38	0.4	31
2004	69	52	43	46	20	38	0.4	31
2005	72	52	42	46	20	38	0.8	28
2006	76	53	44	47	16	38	0.7	29
2007	77	53	45	47	16	38	0.5	31
2008	87	53	59	48	13	37	0.5	31
2009	78	53	47	47	13	36	0.7	30
2010	66	52	46	46	13	36	0.8	30
2011	59	52	46	46	14	35	0.8	29
2012	51	53	42	47	13	35	0.7	30

## Discussion

The 2 main findings of our bi-nationwide study conducted in Finland and Sweden were that the incidence of arthroscopy for knee OA has decreased in both countries (in Finland since 2006 and in Sweden since 2008), and that the overall incidence of knee arthroscopy due to degenerative knee disease and traumatic meniscal tears was almost 4 times higher in Finland than in Sweden. In Finland, the incidence of arthroscopy for degenerative meniscal tears has decreased since 2007, but there has been a simultaneous increase in debridement surgery for meniscal lesions coded as traumatic meniscal tears. Additionally, the mean age of these patients has increased. In Sweden, the incidence of debridement arthroscopy for both

degenerative meniscal injuries and injuries coded as traumatic has been practically unchanged and in contrast to Finland, the mean age of patients with traumatic tear has decreased.

Previous studies have found similar changes in the incidence of knee arthroscopy. A 49% overall increase in knee arthroscopies in the USA between 1996 and 2006 has been reported (Kim et al. 2011); the incidence of arthroscopy for OA decreased while the incidence of meniscal tears increased. Potts et al. (2012) reported a decrease in arthroscopy for OA according to the American Board Exam when comparing the results in 1999 with those in 2009. A report from England and Ontario, Canada, showed that the number of knee arthroscopies for OA had decreased from 1993 to 2004, while the number of knee arthroscopies for meniscal tears had increased

(Hawker et al. 2008). This change in practice was evident after the publication of highly cited articles demonstrating a lack of efficacy of knee arthroscopy in OA (Moseley et al. 2002, Kirkley et al. 2008). Accordingly, the current treatment guidelines stand against knee arthroscopy for the treatment of established OA (Zhang et al. 2010, Brown 2013). Scientific evidence demonstrating the lack of efficacy of arthroscopic treatment for knee OA may also be the main cause of the decline in surgery rates in Finland and Sweden.

Although the incidence of knee arthroscopy for OA has decreased worldwide, the incidence of arthroscopy for meniscal tears has increased. Most recently, Thorlund et al. (2014) from Denmark reported that the incidence of meniscus surgery had doubled from 2000 to 2011 (the annual incidence increased from 164 to 312 per  $10^5$  person-years). Furthermore, in their other study the increase in incidence was seen especially in the private sector (Hare et al. 2015). In addition, quite remarkably, the incidence increased 3-fold in patients over 55 years of age (Thorlund et al. 2014). These findings are consistent with ours, as the data were extracted from a National Patient Register in a Scandinavian country similar to those in the current binational study. Moreover, Lazic et al. (2014) reported a similar increase in meniscus surgery for patients over 65 years of age in the UK between 2000 and 2012. In the present study, the incidence of surgery for degenerative meniscal tears increased in Finland from 1997 to 2007, but not in Sweden. Although the incidence in Finland has declined since 2007, the incidence of knee arthroscopy for degenerative meniscal tears was still 3 times higher than that in Sweden in 2012 and the patients were markedly older in Finland than in Sweden.

There is no clear explanation for the difference in the incidence of knee arthroscopy between Finland and Sweden. It is not likely that the difference in these rather similar Scandinavian countries could be fully explained by a different incidence of knee degeneration or trauma. Cultural issues may also play a role. Geographical variations in surgical procedures result mainly from differences in physician beliefs about the indications for surgery, and the extent to which patient preferences are incorporated into treatment decisions, while a smaller degree of variation in regional surgery rates is due to differences in illness burden, diagnostic practices, and patient attitudes (Birkmeyer et al. 2013, Hare et al. 2015). Financial incentives also influence the practice patterns of physicians (Mitchell 2010, Hare et al. 2015). In addition, the number of knee MRIs and knee arthroscopies performed appears to be correlated (Hare et al. 2015). A recent Danish study revealed that the incidence of meniscus surgery in Denmark is twice as high as that in Finland, and 6 times higher than that in Sweden (Thorlund et al. 2014). The great differences in the numbers of arthroscopic debridement procedures performed in these Scandinavian countries can be compared to the variations in the incidence rates of knee arthroplasty. A recent study showed that the incidence of primary total knee replacements was 180 per  $10^5$  person-years in Finland, 110 per  $10^5$  person-

years in Sweden, and 140 per  $10^5$  person-years in Denmark (Kurtz et al. 2011).

While the incidence of arthroscopy for degenerative meniscal tears began to decline in Finland in 2007, there was an increase in the incidence of arthroscopy for meniscal tears, coded as traumatic but undergoing debridement. It is noteworthy that 44% of all meniscal tears were coded as traumatic in Finland, as compared to 24% in Sweden. In addition to the above-mentioned reasons for the different incidences of procedures between these countries, there may be differences in coding. A change in coding for meniscal tears may have occurred in Finland, because the mean age of patients with meniscal tears coded as traumatic increased from 42 to 46 years. There was no change in either the incidence or the mean age, however, in Sweden. A change in coding was put forward to explain the increase in meniscus surgery in the USA between 1996 and 2006 (Kim et al. 2011). Since 2004, Medicare has not paid for knee arthroscopy performed to treat OA. Thus, for insurance authorization, many cases that would have had a diagnostic code for knee OA may have been coded more recently as meniscal tears because many knees with OA also show degenerative meniscal tears (Englund et al. 2008, Kim et al. 2011). In Finland, part of these procedures are financed by insurance companies, and treated in private hospitals, but only if the tear is coded as traumatic. This may cause orthopedic surgeons in Finland to more frequently code meniscal tears as traumatic rather than degenerative. Differentiating whether a tear is traumatic or non-traumatic (degenerative) is often clinically difficult, and there may be variations between surgeons and patients regarding interpretation of the etiology of the knee complaints. In addition, some patients with traumatic meniscal tears could still seek medical advice after a period of nonoperative treatment, leading to a tear being coded old (degenerative). Also, some patients with degenerative tears have an acute/sudden onset of symptoms with or without a clear knee injury, and these are therefore coded as traumatic (Drosos and Pozo 2004). Based on the current literature, only 5–15% of all treated meniscal tears are traumatic (Metcalf and Barrett 2004, Christoforakis et al. 2005, Camanho et al. 2006), and according to a report from the USA, 75% of patients undergoing meniscus repair are under 35 years of age (Abrams et al. 2013). The incidence of meniscus repairs in our study remained low and unchanged during the study period in both Finland and Sweden. These facts argue against a true change in the incidence of traumatic meniscal tears—and rather for a change in coding.

One strength of our study is that the results reflect actual treatment policies and practices of Finnish and Swedish orthopedic surgeons, and that we used true population-based binational data. The coverage of the study can be considered to be excellent, as medical treatment is equally available to everyone in Finland and Sweden. The NHDRs used in Finland and Sweden have excellent coverage and accuracy (Mattila et al. 2008, Ludvigsson et al. 2011). Thus, we feel that the declining trend in the proportion of operative treatments for

degenerative knee disease represent the real current opinion of Finnish and Swedish physicians treating these disorders.

A limitation of our study was that 2 large hospitals in Sweden had to be excluded from the analysis due to suspicion of double-coding of operations in 2012 in the SNHDR (Socialstyrelsen 2009, Socialstyrelsen 2014). We excluded these hospitals for the entire study period between 2001 and 2012, so our results may underestimate the real incidence of knee arthroscopy in Sweden by about 15%. In addition, although our decision to differentiate the incidence numbers as those with knee OA, those with degenerative meniscal tears, those with traumatic tears with debridement, and those with traumatic tears with repair is consistent with clinical practice; it may not reflect the reality behind the registry data, as it is not possible to have information on more detailed arthroscopic findings or individual patient history. Besides, it is often difficult to make a diagnosis; the coding may also be influenced by other factors. As discussed above, there are factors that are not dependent on the true nature of the disease—such as habits, cultural considerations, and insurance policies—that could affect diagnostic coding and the categorization used in this study. Indeed, our results suggest that there is a difference in coding between the 2 countries and that the coding may have changed, particularly for meniscus tears in Finland. However, the mean ages and the actual surgical procedure give us a reliable clue to the nature of the disease. In that vein, our results are more accurate than using the diagnosis code alone and suggest that the vast majority of patients undergoing meniscus surgery have degenerative—not traumatic—pathology of the knee.

In conclusion, the incidence of arthroscopy for knee OA declined similarly during the study period in Finland and Sweden. In Finland, but not in Sweden, the incidence of meniscus surgery increased during the same period. Furthermore, in Finland a substantial proportion of meniscal tears were coded as traumatic, a practice that is not supported by the mean age of the patients or the surgical procedures. We are currently witnessing a notable shift in the indications for knee arthroscopy. 7 high-quality randomized controlled trials assessing the benefit of arthroscopic partial meniscectomy for patients with degenerative meniscal tears were recently published (Østerås et al. 2012, Herrlin et al. 2013, Katz et al. 2013, Sihvonen et al. 2013, Yim et al. 2013, Gauffin et al. 2014, Stensrud et al. 2015). Only 1 of these trials (Gauffin et al. 2014) provided any support for surgery of the degenerative knee. Implementation of evidence takes several years before it is detected in nationwide registry studies. As we have data regarding the incidence of knee arthroscopy until 2012, we could not detect possible changes in the number of arthroscopies performed for degenerative knee disease—namely degenerative meniscus—after the latest evidence was published. The national variations in the surgical trends in degenerative knee disease between Finland and Sweden are remarkable. Further investigation is needed to determine the reasons for these trends, such as differences in reimbursement.

VM and JP were responsible for acquisition of data, and for analysis and interpretation of data. VM, RS, and LT were responsible for the study design. VM and RS wrote the first draft of the manuscript.

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