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Degenerative isolated cartilage defects of the patellofemoral joint are associated with more severe symptoms compared to trauma-related defects: results of the German Cartilage Registry (KnorpelRegister DGOU)

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Abstract

Purpose The purpose of this study was to utilize data from the German Cartilage Registry (KnorpelRegister DGOU) to examine the hypothesis that degenerative cartilage defects of the patellofemoral joint are associated with more severe clinical symptoms compared to trauma-related defects.

Methods All patients with isolated focal cartilage defects of the patellofemoral joint registered in the German Cartilage Registry until May 2017 were included in the study. Patients with previous surgery of the ipsilateral knee were excluded. Baseline data including etiology (traumatic, degenerative), size, location and ICRS grade of the cartilage defects as well as the duration of symptoms were analyzed. Clinical symptoms were evaluated by means of the numeric analog scale (NAS) for pain and the Knee injury and Osteoarthritis Outcome Score (KOOS). Group comparisons were performed using the Mann–Whitney-U test along with the Chi-squared test and Fisher's exact test. A bivariate correlation analysis and a multivariable linear regression analysis were performed to investigate the association between the defect characteristics and the clinical scores.

Results A total of 423 patients (203 traumatic and 220 degenerative defects) were included. Isolated degenerative cartilage defects were found to have significantly more trochlear locations (28% vs. 18%; $p = 0.006$), significantly less ICRS grade 4 lesions (50% vs. 73%; $p = 0.002$) and a significantly smaller defect size [median 300 (IQR 105–400) vs. 300 (200–400) mm^2] when compared to those from traumatic etiology. Traumatic defects showed significantly better KOOS-ADL [77 (60–90) vs. 69 (56–82); $p = 0.005$], KOOS-pain [69 (56–81) vs. 61 (47–75); $p = 0.001$] and NAS [2 (1–5) vs. 4 (1–6); $p = 0.005$] scores compared to degenerative defects. The correlation analysis revealed only weak correlations between the quantitative defect characteristics and clinical scores.

Conclusions Degenerative isolated cartilage defects in the patellofemoral joint are associated with more severe clinical symptoms in comparison to trauma-related defects. Additionally, they show a larger variance regarding their location with more trochlear defects.

Level of evidence III.

Keywords Cartilage defect · Patellofemoral · Knee · Registry · Pain

Introduction

Large-scale arthroscopic studies have demonstrated that the main sites of cartilage defects in the knee are the medial femoral condyle (32–58%) followed by the patella (11–34%) [1, 2, 10, 32]. With regards to isolated full thickness cartilage defects, the patellofemoral joint is affected as frequent as the medial knee compartment in patients under the age

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of 40 years [2]. However, clinical outcomes after operative treatment of patellofemoral cartilage defects have shown to be variable and problematic in comparison to other locations of the knee [17, 19, 20, 23, 27]. One reason might be the distinct inhomogeneity of affected patients. The main etiological factors for chondral injuries of the patellofemoral joint are generally from acute trauma or pathologic load distribution [8]. However, there are also cases without apparent cause for the defect. Additionally, defects of the patellofemoral cartilage show a wide range regarding size and location within the patellofemoral joint. This is further complicated by the variability in its clinical presentation. For example, Wang et al. evaluated cartilage changes after previous partial medial meniscectomy in 158 completely asymptomatic patients (30–55 years) and detected a prevalence of patellofemoral cartilage defects of 17% [31]. On the other hand, patellofemoral cartilage defects can provoke severe anterior knee pain [3]. Although there is no direct evidence that these symptoms are originating from the cartilage defect, several clinical studies have demonstrated the efficacy of surgical repair of these patellofemoral defects [5, 7, 12, 16, 21, 26, 30].

Often times patients present with concomitant disorders such as patellofemoral maltracking and functional disorders of the lower extremities that may contribute to this generalized anterior knee pain [6, 11, 22, 29]. Given these complex interactions, isolating symptomatic cartilage defects of the patellofemoral joint, is a major challenge for clinicians. To date, the knowledge about which factors are associated with the severity of symptoms in patients with patellofemoral cartilage defects is limited.

The purpose of present study was to investigate the morphology (location, size, grade) and the associated clinical symptoms of isolated patellofemoral cartilage defects in a large patient cohort, and to investigate if there is a correlation with the defects' etiology.

It was hypothesized that degenerative focal cartilage defects of the patellofemoral joint will be associated with more severe symptoms and will present with a different defect morphology in comparison with trauma-related defects.

Materials and methods

All patients with isolated focal cartilage defects of the patellofemoral joint, who were registered in the German Cartilage Registry (KnorpelRegister DGOU) from October 2013 until May 2017, were included in this study. The German Cartilage Registry is a multicenter registry in Germany, Switzerland and Austria, which was introduced in October 2013 and aims on evaluating patients who underwent treatment of focal cartilage defects [18]. Data were collected by means of a web-based Remote Data Entry system and was recorded by both the physicians and the patients. Patients with a history of previous surgery on the ipsilateral knee joint were excluded.

Data acquisition

The Baseline data of the registry include information about the present pathology and the performed treatment, as well as information about the patient's preoperative symptoms. The etiology of the cartilage defect was differentiated into either traumatic or degenerative etiologies. Regarding the data entry in the registry, trauma was defined as sudden, unexpected event causing damage to the knee joint. Traumatic defects are further differentiated into early (history of trauma $\leq$ 12 months ago) or late (history of trauma > 12 months ago) traumatic defects. The duration of symptoms was given in months. The morphologic characteristics of the cartilage defects were recorded by the surgeon based on the intraoperative findings. The defect size was determined using its maximum width and length in millimeter (mm). To make the size comparable, both values were multiplied and the final value was given in mm^2. The severity of the cartilage defect was classified into four grades according to the ICRS classification. The locations of the defect were described based on the following sites: lateral patella facet, medial patella facet, patella ridge, lateral trochlea, medial trochlea and central trochlea. Additionally, a broader classification was used to group the defect into 1 of 3 locations: patellar, trochlear or combined location.

The clinical symptoms of the patients were evaluated by means of the numeric analog scale (NAS) for pain and the Knee injury and Osteoarthritis Outcome Score (KOOS). The results of the KOOS are given as an overall score (KOOS) and then was further divided according to its subscales including activities of daily living (KOOS-ADL), pain (KOOS-pain), quality of life (KOOS-QOL), symptoms (KOOS-symptoms) and sports (KOOS-sports) [24].

The German Cartilage Registry is conducted in accordance with the 1964 Declaration of Helsinki and registered at germanctr.de (DRKS00005617). The registration of data was approved by the local ethics committees of every participating institution. Primary approval was given by the ethics committee at the University of Freiburg (No. 520/14). Informed consent was obtained from all individual participants included in the study.

Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics version 24 (IBM Corp., Armonk, NY, USA) and R 3.4.2 (R Foundation for Statistical Computing, Vienna, Austria). Statistical hypothesis testing was performed on

two-sided exploratory 5% significance level. The distribution of continuous variables was presented by median and interquartile range (IQR). Categorical variables were described by absolute and relative frequencies.

Hypothesis testing on the 2 etiological subgroups regarding differences in the defect's characteristics and the clinical symptoms was performed using the Mann–Whitney-*U* test for continuous variables and the Chi-squared test or Fisher's exact test for categorical variables.

The association between etiological and morphological characteristics of the cartilage defect to clinical symptoms (NAS, KOOS) was investigated by means of bivariate correlation analysis using Spearman's correlation coefficient (*r*). A corresponding multivariable analysis was performed by stepwise forward variable selection based on Akaike's information criterion (AIC) that also allowed for the inclusion of any higher order interaction effects to construct multivariable linear regression models using the predictor variables including defect etiology, duration of symptoms, defect location, defect grade and defect size. The sample size of 423 patients available from the registry was sufficient for any of the aforementioned analyses. In the most complex analysis using multivariable linear regression models, it allowed for the consistent estimation of up to 42 regression coefficients [9].

Results

There were 423 patients identified in the registry presenting with isolated patellofemoral cartilage defects without a history of previous surgery at the relevant knee joint (Fig. 1). Of these patients, 203 (48%) had traumatic cartilage defects while 220 (52%) had degenerative cartilage defects. Among the patients with traumatic cartilage defects, 135 cases had the trauma within 12 months, compared to 68 cases where the traumatic event was sustained greater than 12 months prior to presentation.

Comparison of the etiological groups

Comparison between the two etiological groups revealed significant differences regarding all morphological defect characteristics (Table 1). In particular, patients with degenerative defects showed significantly more defects at the trochlea, significantly less grade 4 defects and a significantly smaller defect size.

Regarding clinical symptoms, degenerative defects showed significantly lower scores in comparison with trauma-related defects for the KOOS-ADL, KOOS-pain and NAS (Table 2; Figs. 2, 3).

The subgroup analysis between patients who had an early trauma (< 12 months ago) and patients with late trauma (> 12 months ago) showed a significantly higher rate of

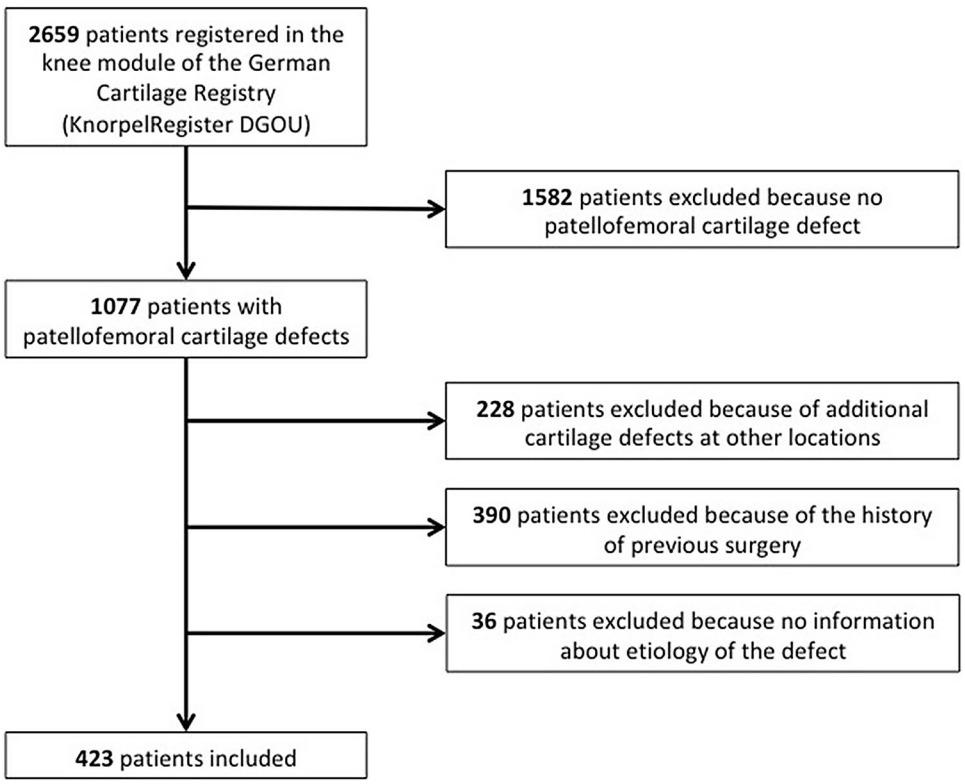

Fig. 1 Flowchart of the development of the included patient cohort

Table 1 Results of the epidemiologic and morphologic defect characteristics in comparison between the 2 etiological groups

	Traumatic ($N=203$)	Degenerative ($N=220$)	p value
Age (years)	26 (22–36)	38 (27–46)	<0.001
Sex (female/male)	83 (41%)/118 (59%)	95 (43%)/125 (57%)	n.s
Duration of symptoms (months)	6 (2–18)	12 (6–24)	<0.001
Defect location			
Patella	155 (76%)	149 (68%)	0.006
Medial	53 (26%)	27 (12%)	
Lateral	12 (6%)	17 (8%)	
Ridge	90 (44%)	105 (48%)	
Trochlea	36 (18%)	62 (28%)	
Medial	5 (3%)	14 (6%)	
Lateral	5 (3%)	7 (3%)	
Central	26 (13%)	41 (19%)	
Patella and trochlea	12 (6%)	9 (4%)	
Defect grade			
Grade I	0 (0%)	0 (0%)	0.002
Grade II	3 (1%)	3 (1%)	
Grade III	65 (26%)	105 (48%)	
Grade IV	134 (73%)	110 (50%)	
Defect size (mm^2)	300 (200–400)	300 (105–400)	0.016

Qualitative variables are given in absolute (relative) frequencies. Quantitative variables are given in median (IQR)

n.s. Non-significant

Table 2 Results of the clinical scores in comparison between the etiological groups

	Traumatic	Degenerative	p value
KOOS	62 (47–74)	58 (47–69)	n.s
KOOS-ADL	77 (60–90)	69 (56–82)	0.005
KOOS-pain	69 (56–81)	61 (47–75)	0.001
KOOS-QOL	31 (19–44)	31 (19–44)	n.s
KOOS-symptoms	64 (46–79)	64 (54–75)	n.s
KOOS-sport	30 (10–51)	30 (10–50)	n.s
NAS	2 (1–5)	4 (1–6)	0.005

The values are given in median (IQR)

n.s. Non-significant

grade 4 defects among early defects. Additionally, patients with late defects showed significantly worse results for the KOOS-Pain and KOOS-QOL (Table 3).

Association between defect characteristics and clinical symptoms

The bivariate correlation analysis between the quantitative defect characteristics and clinical scores was performed separately for patients with traumatic cartilage defects and for patients with degenerative cartilage defects (Tables 4, 5). Among patients with traumatic cartilage defects, there was a significant negative correlation between the duration of symptoms and KOOS-QOL, as well as a significant negative correlation between defect size and NAS. Furthermore, the duration of symptoms showed a significant positive correlation with the defect size and a significant negative correlation with the defect grade. Among patients with degenerative cartilage defects, there was a significant positive correlation between the duration of symptoms and the defect size. The comparison between the different defect locations did not show significant differences with regard to the clinical scores (Tables 6, 7).

The multivariable analysis confirmed that the etiology of the defect was the most significant factor with regard to the clinical symptoms (Table 8). Predictive multivariable models could be defined for the KOOS-Pain and the NAS, while for all other scores none of the evaluated variables were chosen for inclusion in the predictive models based on variable selection.

Discussion

The major finding of this study was that isolated degenerative cartilage defects of the patellofemoral joint were associated with worse clinical scores and more diverse defect morphology in comparison with trauma-related defects. This confirms the hypothesis of the study.

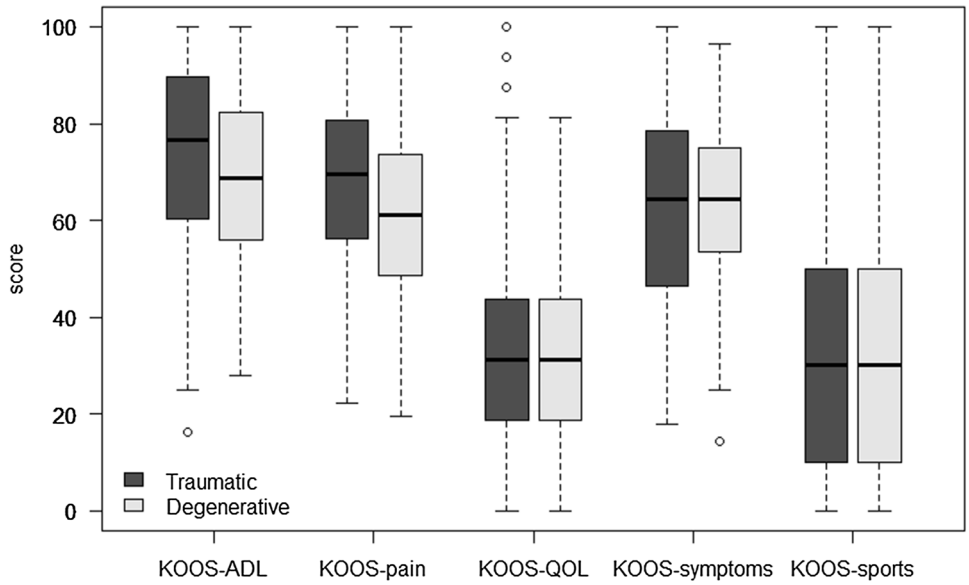

Fig. 2 Box plots of the values of the KOOS subscales in comparison between the 2 etiological groups

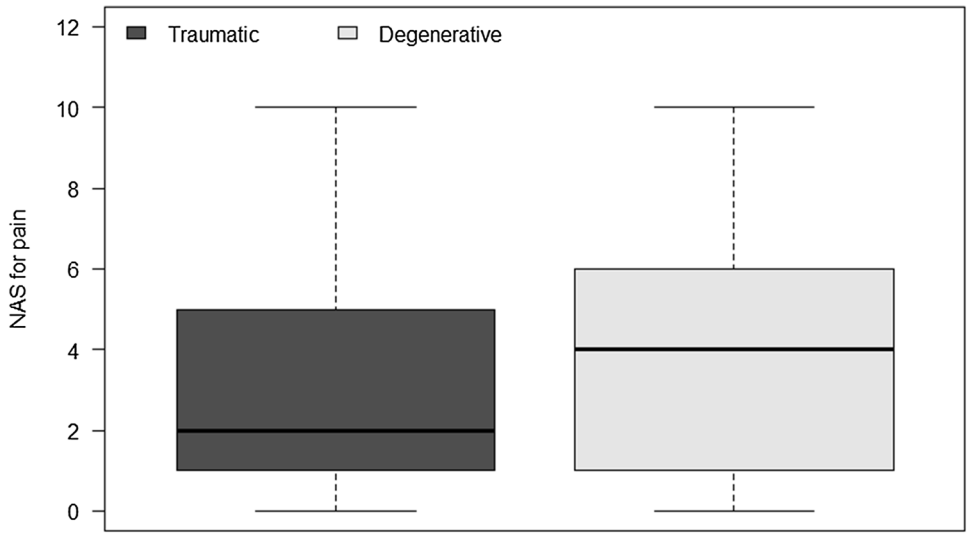

Fig. 3 Box plots of the values of the NAS for pain in comparison between the 2 etiological groups

A cross-sectional study of patients registered in the German Cartilage Registry (KnorpelRegister DGOU) was conducted. Only patients with isolated patellofemoral cartilage defects, without a history of previous knee surgery were included. The large sample size and homogeneous patient population adds to the general strengths of the present study.

The included patients represent a cross-sectional cohort of patients, who received medical treatment for isolated cartilage defects in the patellofemoral joint. Baseline data revealed that the average duration of symptoms until treatment was 21 months, which corresponds to the fact that most of the defects were degenerative in etiology, whereas less than 50% of the defects were trauma related. The high rate of grade 3 or 4 cartilage defects confirms the assumption that low-grade cartilage defects show less clinical signs and hence less need for medical treatment. In accordance with previous studies, which have investigated the location of cartilage defects in the knee joint, the rate for cartilage defects at the patella was three times higher in comparison to the trochlea [1, 2, 10, 32].

This study also confirmed the significant differences in defect morphology between etiology groups. The vast majority of traumatic defects were rated as grade 4, whereas almost half of the degenerative defects were rated as grade 3. Additionally, trauma-related defects were more often located at the patella and showed a predominance in the medial patellofemoral joint. In contrast, degenerative defects showed a larger variance regarding their location with more trochlear located defects compared to those from traumatic etiology. One plausible explanation for this is that patients with traumatic patellar dislocations are at higher risk of full-thickness chondral lesions, especially at the medial patella

Table 3 Morphologic defect characteristics and results of the clinical scores in comparison between patients with early (< 12 months ago) and late (> 12 months ago) traumatic cartilage defects

	Early traumatic (< 12 months) ($N = 135$)	Late traumatic (> 12 months) ($N = 68$)	*p* value
Defect grade			
Grade I	0 (0%)	0 (0%)	0.007
Grade II	1 (1%)	2 (3%)	
Grade III	35 (26%)	30 (44%)	
Grade IV	98 (73%)	36 (53%)	
Defect size (mm^2)	300 (200–400)	374 (250–500)	n.s
KOOS	61 (48–77)	63 (47–72)	n.s
KOOS-ADL	77 (60–91)	77 (60–88)	n.s
KOOS-pain	72 (58–83)	64 (53–75)	0.032
KOOS-QOL	34 (25–44)	25 (13–38)	0.024
KOOS-symptoms	64 (46–79)	68 (48–79)	n.s
KOOS-sport	30 (10–55)	30 (5–50)	n.s
NAS	2 (1–4)	3 (1–5)	n.s

Qualitative variables are given in absolute (relative) frequencies. Quantitative variables are given in median (IQR)

n.s. non-significant

facet [5, 25]. Unfortunately, baseline data collected did not allow for more precise conclusions regarding the exact etiology of the defects.

The results of the present study further revealed that amongst the investigated factors the defects' etiology showed the most significant association with the severity of clinical symptoms. In general, patients with trauma-related defects showed better clinical scores in comparison with degenerative defects. Patients with a history of acute trauma (≤ 12 months) showed less severe symptoms in comparison with posttraumatic defects (> 12 months). In the authors' opinion, the differences seen between traumatic and degenerative defects are most likely caused by the fact that in degenerative cartilage lesions concomitant patellofemoral malalignment plays a more important role [8]. This malalignment leads to pathologic intraarticular load distributions and may be a cause of increased clinical symptoms. Patients with degenerative defects often suffer from steadily increasing pain over a long period before a physician is consulted. In patients with traumatic cartilage defects, on the contrary, the incidence of a trauma may cause an earlier consultation and hence an earlier treatment.

The significant difference between early traumatic and late traumatic defects regarding clinical symptoms indicates a relevant deterioration of these defects over time. This finding is further supported by the fact that a longer duration of symptoms was associated with a worse KOOS-QOL and a higher NAS. Additionally, a significant positive correlation between duration of symptoms and defect size for both

Table 4 Results of the correlation analysis between the quantitative defect characteristics and the clinical symptoms for patients with traumatic cartilage defects

	Duration of symptoms	Defect size	Defect grade
KOOS			
r	− 0.011	0.111	0.045
p value	n.s	n.s	n.s
KOOS-ADL			
r	− 0.031	0.071	0.051
p value	n.s	n.s	n.s
KOOS-pain			
r	− 0.138	0.096	0.086
p value	n.s	n.s	n.s
KOOS-QOL			
r	− 0.201	0.014	0.086
p value	0.017	n.s	n.s
KOOS-symptoms			
r	0.082	0.102	0.031
p value	n.s	n.s	n.s
KOOS-sports			
r	0.003	0.137	0.060
p value	n.s	n.s	n.s
NAS			
r	0.131	− 0.201	− 0.031
p value	n.s	0.017	n.s
Duration of symptoms			
r	–	0.156	− 0.218
p value		0.033	0.002
Defect size			
r	0.156	–	0.095
p value	0.033		n.s
Defect grade			
r	− 0.218	0.095	–
p value	0.002	n.s	

r Spearman's correlation coefficient; *n.s.* non-significant

degenerative and traumatic defects was found, which confirms the relevant deterioration over time and is in accordance with previous findings. Salonen et al. recently published the results of a MRI based study on 20 patients with first-time traumatic lateral patellar dislocation and found a significant decline of the patellar cartilage in the period between the trauma and a mean follow-up of 8 years [25].

For both degenerative and traumatic defects, correlation analysis showed only weak or very weak correlation between the clinical symptoms and the defects' size, location or grade. In general, the present study shows that the morphology of patellofemoral cartilage defects does not serve as a good indicator for the severity of pain or altered joint function. To date, there is very limited data about the association between focal cartilage lesions and clinical

Table 5 Results of the correlation analysis between the quantitative defect characteristics and the clinical symptoms for patients with degenerative cartilage defects

	Duration of symptoms	Defect size	Defect grade
KOOS			
r	0.024	0.012	0.084
p value	n.s	n.s	n.s
KOOS-ADL			
r	0.025	0.020	0.096
p value	n.s	n.s	n.s
KOOS-pain			
r	0.004	0.089	0.073
p value	n.s	n.s	n.s
KOOS-QOL			
r	− 0.041	0.048	− 0.014
p value	n.s	n.s	n.s
KOOS-symptoms			
r	0.018	− 0.081	− 0.007
p value	n.s	n.s	n.s
KOOS-sports			
r	0.025	− 0.011	0.093
p value	n.s	n.s	n.s
NAS			
r	0.079	0.120	0.002
p value	n.s	n.s	n.s
Duration of symptoms			
r	–	0.144	− 0.007
p value		0.040	n.s
Defect size			
r	0.144	–	− 0.045
p value	0.040		n.s
Defect grade			
r	− 0.007	− 0.045	–
p value	n.s	n.s	

r Spearman's correlation coefficient, *n.s.* non-significant

Table 6 Results of the clinical scores in comparison between the different defect locations for patients with traumatic cartilage defects

	Patella	Trochlea	Patella and trochlea	*p* value
KOOS	61 (46–74)	62 (48–73)	67 (56–77)	n.s
KOOS-ADL	75 (58–89)	77 (64–91)	83 (68–93)	n.s
KOOS-pain	67 (53–79)	75 (58–87)	74 (63–85)	n.s
KOOS-QOL	31 (19–44)	28 (16–39)	38 (25–58)	n.s
KOOS-symptoms	68 (46–79)	59 (49–80)	64 (49–79)	n.s
KOOS-sports	30 (6–54)	25 (10–53)	40 (25–53)	n.s
NAS	3 (1–5)	2 (0–4)	2 (0–4)	n.s

The values are given in median (IQR)

n.s. non-significant

Table 7 Results of the clinical scores in comparison between the different defect locations for patients with degenerative cartilage defects

	Patella	Trochlea	Patella and Trochlea	*p* value
KOOS	58 (46–67)	57 (47–71)	63 (52–70)	n.s
KOOS-ADL	69 (55–82)	67 (51–83)	78 (61–93)	n.s
KOOS-pain	61 (47–72)	63 (55–78)	62 (59–66)	n.s
KOOS-QOL	31 (19–43)	25 (19–44)	38 (28–47)	n.s
KOOS-symptoms	63 (50–75)	70 (54–80)	64 (58–76)	n.s
KOOS-sports	30 (12–50)	30 (10–50)	25 (10–50)	n.s
NAS	4 (2–6)	2 (1–6)	5 (3–7)	n.s

The values are given in median (IQR)

n.s. non-significant

Table 8 Results of the multivariable analysis

	Model	β-coefficient	SE	*p* value
KOOS	*			
KOOS-ADL	Intercept (reference)	72.5	1.6	
	Degenerative etiology	− 4.3	2.3	n.s
KOOS-pain	Intercept (reference)	63.1	2.5	
	Degenerative etiology	− 5.5	2.1	0.011
	Trochlea location	4.6	2.5	n.s
	Defect size (cm^2)	0.8	0.5	n.s
KOOS-QOL	*			
KOOS-symptoms	*			
KOOS-sports	*			
NAS	Intercept (reference)	3.2	0.2	
	Degenerative etiology	0.8	0.3	0.012
	Trochlea location	− 0.6	0.4	n.s

Models created by stepwise forward variable selection according to Akaikes's information criterion

SE standard error, *n.s.* non-significant

*Null model (intercept only)

symptoms. Solheim et al. conducted a prospective study on 1000 patients who underwent knee arthroscopy including microfractures of cartilage defects and ACL reconstructions [28]. 57% percent (565 patients) of these patients showed chondral or osteochondral cartilage defects. They found kissing lesions and multiple lesions to be significantly correlated with worse clinical symptoms and decreased joint function, whereas size, grade and location of the cartilage defects showed a very weak correlation. However, one major limitation of this study was the heterogeneity of the included patients regarding the indication for surgery. Furthermore, there was no information about previous surgeries, the injuries' etiology or the duration of symptoms. To represent a

homogeneous patient collective, the present study focused on patellofemoral cartilage defects only. In comparison with other locations of the knee joint, patellofemoral lesions are still challenging with less predictable results after cartilage repair surgery [17, 19, 20, 23, 27]. Therefore, a better understanding of the etiology and morphology of these cartilage defects and their correlation with the clinical symptoms are important.

Along with certain strengths, there are limitations to this study. First, this is a cross-sectional cohort study based on data collected in a multicenter registry. Therefore, the general limitations of registry studies apply to this study as well, including the variability regarding the evaluation and registration of the data among the participating surgeons. However, high-quality registries give the opportunity to investigate large patient collectives and to create homogeneous study groups, which is why this study design is particularly applicable for the present study.

A further limitation of this study is the lack of more detailed information about the etiology of the defects. Knowledge regarding the rate of patients with traumatic patella dislocations would have been desirable. Additionally, the registry data does not offer information about the presence of possible co-pathologies that correlate with patellofemoral malalignment. As these are known factors that correlate with the presence of patellofemoral cartilage defects, the investigation of a possible correlation with the clinical symptoms would be of interest [4, 13–15].

The findings of the present study are of relevant clinical importance, as orthopaedic surgeons must not be misled by the size or the grade of patellofemoral cartilage defects, since these factors do not show relevant correlations with the clinical symptoms. Instead, factors that lead to chronic overload or instability, and hence to degenerative cartilage defects should be given greater consideration as these defects correlate with more severe symptoms. Therefore, possible co-pathologies must be evaluated preoperatively and taken into account when cartilage repair surgeries are planned. A further important clinical aspect of the present study is that traumatic cartilage defects in the patellofemoral joint show a significant worsening in defect size and severity of symptoms over time. Therefore, these patients should be followed closely and appropriate therapy must not be delayed.

Conclusions

Degenerative focal cartilage defects in the patellofemoral joint are associated with more severe clinical symptoms in comparison to trauma-related defects. Additionally, they show a larger variance regarding their location with more trochlear located defects.

Author contributions All authors contributed to the conception and design of the study. All authors except for AH were responsible for acquisition of data. JM, AO, AH and AS contributed to analysis and interpretation of data. All authors were responsible for drafting or revising the article and approved the final version of this manuscript.

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Compliance with ethical standards

Conflict of interest P.A. reports consulting for Arthrex and Aesculap outside the submitted work. P.N. reports consulting for Arthrex and honoraria from Codon, Stryker and Aesculap outside the submitted work. A.B.I. reports consulting for Arthrosurface and medi and royalties from Arthrex and Arthrosurface outside the submitted work. W.Z. reports grants from Codon and honoraria from Plasmaconcept outside the submitted work. All other authors declare that they have no conflicts of interest.

Ethical approval The German Cartilage Registry is conducted in accordance with the 1964 Declaration of Helsinki and registered at germanctr.de (DRKS00005617). The registration of data was approved by the local ethics committees of every participating institution. Primary approval was given by the ethics committee at the University of Freiburg (No. 520/14).

Informed consent Informed consent was obtained from all individual participants included in the study.

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