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A proposal of a new periimplant breast pathology classification into 3 types

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Despite preventive measures, silicone breast implants can develop severe pathologies that necessitate surgical revision. At present, there is no standardized classification for the capsular tissue excised during such revisions, yet establishing one would be critical for elucidating the underlying causes and pathogenesis of implant failure. A histopathological typing scheme for capsular tissue in breast implant-related pathologies (PBI classification) was developed and its sensitivity compared with the clinical diagnosis. A newly adapted, substantially time-reduced Oil Red O staining protocol is to be applied to assess whether direct detection of silicone is sufficiently feasible. Three types were defined: fibrosis type 1 is characterized by a fibrous reaction with variable fibroblast cellularity. Silicone type 2 is defined by the presence of silicone deposits within and outside the capsular tissue. Malignancy type 3 is characterized by the presence of malignancies. A total of 150 cases from five different clinics (period: 2001–2018) were characterized as follows: fibrosis type 1, $n = 104$ (69.3%); silicone type 2, $n = 42$ (28.0%); malignancy type 3, $n = 4$ (2.7%). The sensitivity of clinical diagnosis for breast implant-related pathologies was 80.8%, 95% CI [71.9%, 87.4%] for fibrosis type 1; 54.8%, 95% CI [38.7%, 70.2%] for silicone type 2; and 0%, 95% CI [0%, 17.7%] for malignancy type 3. This classification makes a significant contribution to elucidating their etiology. The results for the interobserver ($\kappa = 0.87$) and intraobserver ($\kappa = 1.0$) reliability showed a high agreement, which adds to the robustness and reproducibility of this classification. Comparison of histopathological and clinical diagnoses revealed a marked discrepancy in the correct identification of silicone type 2. The newly adapted time shortened and readily applicable Oil Red O staining enables direct detection of silicone and is proposed, in addition to this classification, as a specific method for silicone detection in routine diagnostics.

Keywords Silicone breast implants, Implant pathologies, Silicone extravasation, Implant revision, Classification

Breast implants are used for cosmetic breast augmentation, correction of asymmetries, and gender-affirming surgery. They are also successfully applied in breast reconstruction after mastectomy or in preventive surgery to reduce breast cancer risk in women. Breast implants are among the most extensively tested medical devices on the market[1], and patient satisfaction improves significantly[2]. The shell of these devices typically consists of an outer silicone elastomer layer, while the proportion of silicone and/or saline in the filling material varies by manufacturer. Implants are available with textured (macro- or micro-) or smooth surfaces[3].

In contrast to the now internationally accepted and routinely applied histopathological classification of joint implant-related pathologies[4–6], no such classification exists for breast implant-related pathologies[7–10]. In Germany, only a purely clinically based registry is maintained (www.ago-online.de/news/implantateregister), which, since 2021, has been organized predominantly in a "test operation" phase. The registry notes: "Estimates suggest that approximately 66,000 breast implants are used annually in Germany, of which only around 7000 are for breast reconstruction; the majority are used for aesthetic purposes." Histopathological data, which would be essential, are not included. Furthermore, there is a lack of uniformly defined histopathological criteria and a

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corresponding classification system that would enable comprehensive and consistent etiological categorization of breast implant-related pathologies in routine diagnostics. Although the criteria of Wilflingseder et al.[11,12] provide a classification of pathologies in silicone breast implants, they only cover the histological description of capsular fibrosis (capsular contracture). Prantl et al.[13] compared this classification system with the clinically relevant Baker grading system for capsular contracture[14]. However, a comprehensive classification that, in addition to fibrosis, also incorporates the pathogenesis of silicone extravasation and malignancy is still lacking.

Objectives

1. Following the classifications established for joint endoprosthesis pathologies[4–6,15], an analogous classification for pathologies associated with silicone breast implants was developed (PBI classification). It is anticipated that this classification will provide a similar diagnostic benefit as has already been demonstrated for joint endoprosthesis pathology classifications[4–6], and may therefore also carry substantial clinical relevance. The transfer of this concept to silicone breast implants is plausible, as fibrotic disorders, polymer-induced inflammation, and—albeit very rarely—malignant diseases can also occur. Accordingly, three types were defined: Fibrosis Type 1, silicone Type 2, and malignancy Type 3. These three types encompass the most clinically relevant and histopathologically characteristic changes.
2. A technically newly adapted Oil Red O staining protocol, enabling a significantly shortened processing time, was developed to allow for specific and direct detection of silicone in routine diagnostics and to facilitate silicone identification.

Methods

Type 1 is characterized by a fibrotic reaction with variable fibroblast cellularity and a hyalinized matrix. The surface is lined by a synovial-like cell layer[13]. Type 2 describes the detection of silicone extravasation within and/or outside the capsular tissue. Malignancy Type 3 is defined by the presence of malignant tumors, such as breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), as well as invasive and non-invasive breast carcinomas.

Criteria for type definition

Fibrosis type 1

The main characteristic of this type is a highly fibrotic capsular tissue with variable cellular density and thickness, containing fibrotic and hyalinized areas (Fig. 1). Inflammatory infiltration is sparse and mononuclear. Silicone is not detectable. Towards the lumen, a cell layer is present, which may be flat and in part oriented in a polar fashion toward the surface. Histologically, this layer is composed of fibroblast-like or histiocytic cells. In the literature, this appearance has also been described as a synovial-like cell layer[13]. The fibrous tissue exhibits irregular vascularization, and focal calcifications may be present. In this type, there is no histopathological equivalent of a bacterial infection, which would otherwise be characterized by clustered accumulations of neutrophilic granulocytes[4–6].

Silicone type 2

The distinctive feature of this type is the detection of silicone within the pericapsular connective tissue and within the capsule itself (Fig. 2). As in Type 1, a cell layer facing the lumen is also present, which may be flat and in part oriented in a polar fashion toward the surface. This layer likewise consists of fibroblast-like or histiocytic cells[13]. Silicone may be found extracellularly in large vacuole-like structures, intracellularly within macrophages, as well as in aggregates of macrophages. As in Type 1, no histopathological equivalent of a bacterial infection is present, which would otherwise be characterized by clustered accumulations of neutrophilic granulocytes[4–6].

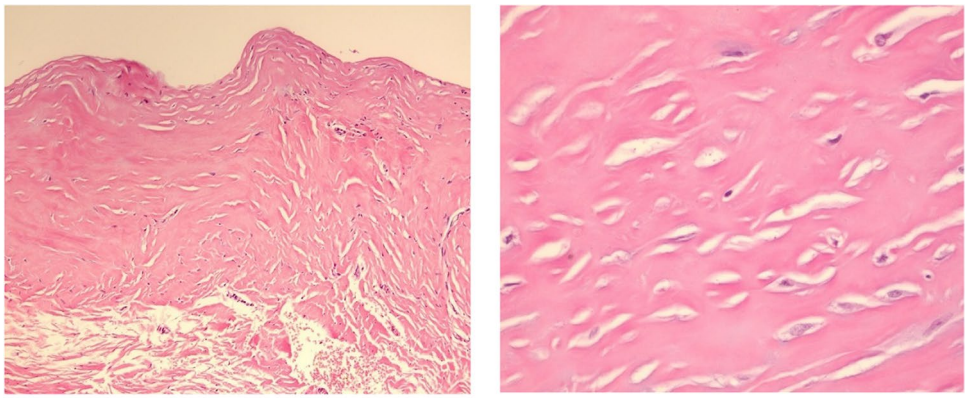


Fig. 1. Fibrosis type 1. Fibrosis type 1 of a textured breast implant. The surface shows well-defined polypoid projections and depressions (**a**) representing the imprint of the microtextured implant surface. The highly fibrotic capsule tissue exhibits variable cellular density and contains fibrotic as well as strongly hyalinized areas (**b**) with a synovial-like covering cell layer. (H&E staining, original magnification ×100 and ×400).

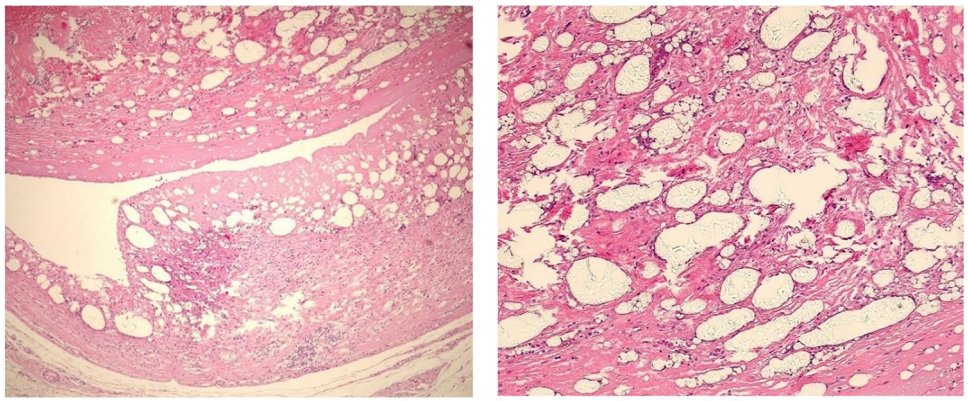


Fig. 2. Silicone type 2. Silicone deposits are partly present in vacuole-like structures and extracellularly, and partly within macrophages, which exhibit broad cytoplasm, indistinct cell borders, and vacuolated, foamy cytoplasmic structures. The surface is bordered by fibroblasts and histiocyte-like cells, as well as macrophages, oriented partly parallel to the surface and partly in a polar manner. Using oblique illumination (**a**), here achieved by maximal lowering of the condenser, silicone appears as brightly glowing, silhouette-like structures (**b**). (H&E staining, original magnification ×100 and ×400).

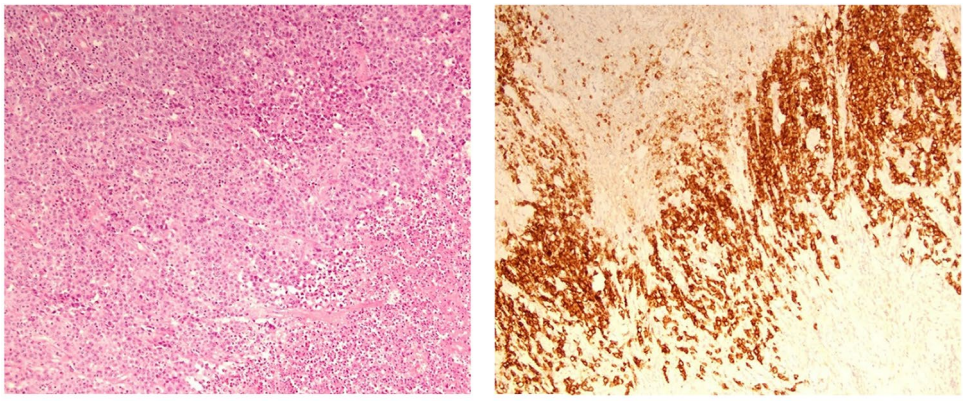


Fig. 3. Malignancy type 3. Malignancy type 3 in the form of a breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). In (**a**), relatively indistinct, confluent blast-like cells are arranged (H&E staining), showing strong CD30 expression in (**b**). (Original magnification ×100).

Malignancy type 3

Malignancy type 3 encompasses all malignant diseases of peri-implant neoplasms that may occur in association with a silicone breast implant. The categorization of this type is based on the updated WHO classification for malignant epithelial tumors of the breast and malignant hematopoietic neoplasms[16]. Malignancy type 3 can, in principle, be subdivided into three subgroups: adenocarcinomas (e.g., recurrence of breast carcinoma, newly developed non-invasive or invasive breast carcinoma), breast implant-associated squamous cell carcinoma (BIA-SCC), and BIA-ALCL (Fig. 3).

Detection method for silicone

Oblique lighting as a contrasting technique

By applying oblique brightfield transmitted light illumination[17] (e.g., by using a specialized aperture, lowering the condenser, or partially tilting the field diaphragm), silicone deposits appear as bright, silhouette-like structures against a darker background, thereby allowing their identification (Fig. 2). This is a simple microscopic technique characterized by eccentrically incident light, which results in higher spatial resolution and permits analysis of additional diffraction maxima. In this way, silicone that is easily overlooked under standard brightfield conditions can also be detected[17]. In most cases, the silicone or silicone deposits consist of liquid silicone gel, representing silicone oil, which can also be released through micro-leakages. This predominantly (≈ 80%) uncrosslinked (therefore low-crosslinked), silicone oil can penetrate the outer elastomer shell—a phenomenon referred to as "bleeding."

Oil Red O stain

In a biopsy-based case series[18], Oil Red O–positivity of silicone in various organs was described for the first time. In the present analysis, a newly adapted Oil Red O staining protocol with a markedly shortened processing time (from 5 days to approximately 18 h) was developed and established as a non-instrumental staining method for the specific detection of silicone in capsular tissue (see supplementary material).

Dataset

The total of 150 cases originated from the Histopathological Implant Registry of the Working Group on Implant Safety of the German Society for Orthopaedics and Trauma (DGOU) at MVZ-Pathologie Trier, GmbH, and comprised data from five different general surgery clinics and clinics specializing in plastic and/or reconstructive surgery. The registry is based on transferred data from the in-house laboratory information system NEXUS / PATHOLOGIE® (Version 1.22.23.23003, NEXUS AG, Donaueschingen, Germany) into a dedicated database. Using the diagnostic criterion ICD-10: T85 (complications due to other internal prosthetic devices, implants, and grafts), all cases labeled "silicone breast implants" were reviewed, re-evaluated, and subsequently included. The dataset comprises routine cases collected over an 18-year period from 2001 to 2018.

As part of data management, all processes for data acquisition, analysis, documentation, publication, archiving, and scientific access to personal data were conducted in a fully anonymized manner. Standardized, S1-guideline–compliant histopathological tissue processing, macroscopic sectioning, and histopathological diagnostics were performed under accreditation (DIN EN ISO/IEC 17020:2012, Registration number: D-IS-21311-01-00), with histopathological assessments carried out exclusively by board-certified pathologists.

For the purpose of validating interobserver reliability and intraobserver reliability, $n = 16$ cases ($n = 10$ fibrosis type 1, $n = 6$ silicone type 2) were evaluated by two different board-certified observers and again by each observer one week later. Reliability was then evaluated with the Cohens kappa coefficient (κ). For the interobserver reliability the first observer correctly identified all silicone type 2 cases (6 true positive) and all but one fibrosis type 1 (9 true negative, 1 false positive). Observer 2 correctly identified all cases (6 true positive, 10 true negative). The observers agreed on 15 out of 16 cases, which corresponds to a $\kappa = 0.87$ for an almost perfect agreement. Regarding the intraobserver reliability both observers matched the same diagnosis, resulting in a $\kappa = 1.0$ for perfect agreement. Two lymphoma diagnosis (BIA-ALCL) had externally been validated by a reference center for Hematopathology with a complete interobserver reproducibility in the sense of a positive external validation.

Vote from the ethics committee

Under processing number 837.244.17 (11078) "Histopathologisches Implantatregister" ("Histopathological Implant Registry") the study was approved by the Ethics Committee of the State Medical Association of Rhineland-Palatinate, Mainz, Germany, regarding the implementation of the study as a retrospective registry study and the study protocol. The statement issued by the ethics committee guarantees that all methods stated and applied were carried out in accordance with applicable guidelines and regulations. Due to the retrospective nature of the study, the Ethics Committee of the State Medical Association of Rhineland-Palatinate waived the need of obtaining informed consent.

Results

Peri-implant capsule resections

The 150 peri-implant, symptomatic capsular resections or parts thereof originated from five clinics in two federal states and spanned the period from 2001 to 2018. In 125 of 150 cases (83.3%), the resections were from bilateral revisions. In 24 of 150 cases (16.0%), they were from unilateral revisions, and in one case (0.7%) no information was provided. All materials submitted for routine diagnostics had a membranous, capsular appearance with a fibrous cut surface and showed a weight range of 11 g to 44 g. In 3 of 150 resections (2.0%), silicone fragments were macroscopically detectable. The sample diameters ranged from 50 mm to a maximum of 180 mm. Data on the types of silicone implants used, implant durations, and stages (capsular contracture according to Baker) were not available. The cases submitted are based on ultrasound (descriptive, without Baker grading) and/or intraoperative findings, which were send in with the question regarding fibrosis, silicone extravasation, malignancy, or more unspecific suspected diagnoses, which were assessed for concordance with histopathology (i.e. sensitivity).

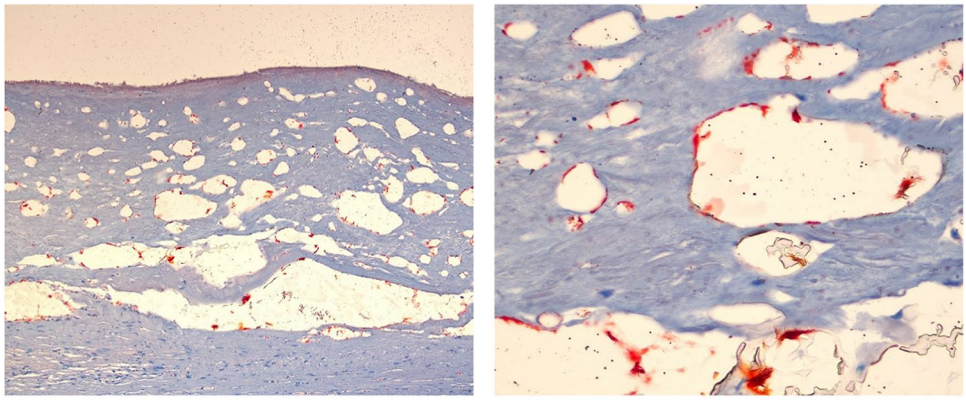
Frequency distribution of the 3 types

Considering the total number of cases (N = 150, mean age = 57.6 years), the distribution of the types was as follows: the most frequent, fibrosis type 1, accounted for $n = 104$ cases (69.3%, mean age = 60.3 years) (Fig. 1). The second most common, silicone type 2, was observed in $n = 42$ cases (28.0%, mean age = 56.3 years) (Fig. 2). Malignancy type 3 was the least frequent, diagnosed in $n = 4$ cases (2.7%, mean age = 55.5 years).

Sensitivity of clinical diagnostics

For fibrosis type 1, the sensitivity analysis revealed the following: of the 104 histopathologically confirmed cases $n = 84$ cases (80.8%) were concordant with the clinical side (true-positive cases). In $n = 20$ cases (19.2%), fibrosis type 1 was not recognized clinically. These false-negative diagnoses included nonspecific terms such as "capsular tissue, right breast." Overall, this corresponds to a sensitivity for fibrosis type 1 of 80.8%, 95% CI [71.9%, 87.4%].

For silicone type 2, the clinical side correctly diagnosed $n = 23$ of the $n = 42$ histopathologically confirmed cases (54.8%). This resulted in $n = 19$ false-negative clinical diagnoses (45.2%), in which the clinical suspicion was capsular fibrosis. The sensitivity for silicone type 2 was therefore 54.8%, 95% CI [38.7%, 70.2%].



(a) (b)

Fig. 4. Detection of silicone using the newly adapted Oil Red O stain. Using Oil Red O staining, an intense orange reactivity is observed in irregularly distributed, predominantly granulomatous structures, with the reactivity in the silicone vacuoles being mostly detectable at the periphery (original magnification ×100 and ×400).

Fibrosis Type 1	Silicone Type 2	Malignancy Type 3
1. Fibrosis Type: Membrane-configured fibrous tissue with variable cellularity of fibroblasts and fibrocytes. Inhomogeneous vascularization. Presence of fibrin deposits, fibrin inclusions, and calcifications. Towards the surface, a limiting layer of polar-oriented fibroblast-like or histiocyte-like cells is present, resembling a synovial-like cell layer. Depending on the type of implant, the surface may be linear or papillary (in the case of textured breast implants) **2. Negative for silicone deposits** **3. Negative for atypical cells** **4. Negative for accumulations of neutrophil granulocytes**	**1. Silicone Type:** Membrane-configured fibrous tissue with embedded silicone deposits, with intra- or extracellular localization Towards the surface, a limiting layer of polar-oriented fibroblast-like or histiocyte-like cells is present, resembling a synovial-like cell layer Evidence of inflammatory changes and calcifications **2. Detection of silicone:** **(a) Oblique illumination** Light microscopic contrast technique **(b) Oil Red O staining** **3. Negative for atypical cells** **4. Negative for accumulations of neutrophil granulocytes**	**1. Adenocarcinomas:** Recurrence of breast carcinoma or newly developed **DCIS** and/or **invasive breast carcinoma (BIA-AC)** **2. Squamous cell carcinoma:** Breast implant-associated squamous cell carcinoma **(BIA-SCC)** **3. Lymphoma** Breast implant-associated anaplastic large cell lymphoma **(BIA-ALCL)**

Table 1. Schematic representation of the 3 peri-implant types: Fibrosis type 1, silicone type 2 and malignancy type 3. DCIS = ductal carcinoma in situ; BIA-AC = breast implant-associated adenocarcinoma.

Malignancy type 3 was not recognized clinically in any case. For the $n = 4$ clinically false-negative diagnoses, the clinical suspicion was "infection and inflammatory reaction." Histopathologically, these cases included microfocal portions of an intermediate-grade ductal carcinoma in situ (DCIS), a well-differentiated invasive adenocarcinoma (not otherwise specified, NOS), and two diagnoses of BIA-ALCL. Accordingly, the sensitivity of clinical diagnostics for malignancy type 3 was 0%, 95% CI [0%, 17.7%].

Detection of silicone: silicone type 2

Using oblique illumination as a simple, easily applied light-microscopic contrast method[17], the brightly luminescent, silhouette-like structures of silicone in peri-implant breast tissue were visualized in all cases of silicone type 2 ($n = 42$) (Fig. 2). The newly adapted Oil Red O staining demonstrated intense orange reactivity in all cases of silicone type 2, appearing as irregular, lamellar, and partially granular structures (Fig. 4).

Discussion

The entire dataset was analyzed according to the three proposed histopathological types (Table 1, Figs. 1, 2, 3). The adaptation of the histopathological classification used for joint endoprostheses (SLIM types) to silicone breast implants proved to be reasonable and feasible, due to the fundamentally comparable and thus transferable histology. In particular, fibrosis type 1 corresponds to SLIM type 4 or 5, silicone type 2 corresponds to SLIM type 1, and malignancy type 3 corresponds to SLIM type 8[4,5, cf. 15].

Classification of the results for fibrosis type 1

In the sensitivity analysis comparing histopathological and clinical diagnoses, a noticeable discrepancy in diagnostic accuracy was observed across all three groups. Fibrosis type 1 was correctly identified clinically in 84

of 104 cases (80.8%). Conversely, 20 of 104 cases (19.2%) were not recognized clinically as pathological capsular fibrosis. It is possible that in these cases the capsular fibrosis was first described through histopathological methods, as physiological capsular fibrosis is not clinically apparent. Nevertheless, the discrepancy between clinical and histopathological diagnoses for type 1 is relatively small. The precise histopathological criteria (e.g., capsule thickness, fibroblast density) required to classify capsular fibrosis as pathological remain unclear. However, since all cases involved revisions with a clinical diagnosis of "capsular fibrosis," the fibrosis observed in these cases can be classified as pathological. Data on the normal fibrous peri-implant membrane without clinical relevance (i.e., without capsular contracture) are currently unavailable and require further investigation.

A histological and immunohistochemical analysis of capsules from fourth-generation smooth-surface breast implants has demonstrated a correlation between the degree of inflammation and the presence of silicone particles with the extent of fibrosis or capsular contracture[13]. The criteria used in this new classification for fibrosis type 1 are based on hematoxylin–eosin histological features. Additional special stains and immunohistochemical analyses, as applied in other studies of capsular fibrosis[13], were omitted here to ensure the practicality of this classification for routine diagnostics.

It should also be noted that capsular fibrosis can be considered dynamic, depending on the implant's dwell time. This applies in both directions, meaning that contracture can both increase and decrease, though the trend is generally toward pathological progression, sometimes accompanied by irreversible calcification.

One possible explanation for the relatively small discrepancy could be the pronounced clinical symptomatology of capsular fibrosis. Fibrosis around the implant is the most common complication of breast implants[19]. Although the etiology of capsular fibrosis is multifactorial and not yet fully understood, it is thought to result from a reaction to the silicone implant, particularly its surface, which is recognized by the body as foreign material[3,13]. For further diagnostics, breast ultrasonography is initially recommended, as it allows measurement of implant wall thickness, providing additional information about possible pathological capsular fibrosis[19].

In summary, pathological capsular fibrosis in breast implants can often already be detected clinically through patient history, various clinical diagnostic methods, and imaging. This likely explains the relatively small discrepancy between clinical and histopathological diagnoses.

Classification of the results for silicone type 2

For histopathological silicone type 2, the clinical diagnosis was correct in 23 of 42 cases, yielding a clinical accuracy of 54.8%. In 45.2% of cases, a different diagnosis was recorded. One possible reason for this substantial discrepancy is that silicone leakage from a defective or ruptured implant, particularly in the case of micro-leakages, is difficult to detect intraoperatively and often remains only suspected. Definitive identification of silicone extravasation is only possible through histopathological examination.

Classification of the results for malignancy type 3

Regarding the diagnosis of the malignancy type 3 there was no concordance between the clinical side and the histopathological diagnosis. All four cases were described as "infection with inflammatory reaction". In regard to the small sample size of only 4 BIA-ALCL cases, the results should be considered indicative until studies with a larger sample are conducted. To further analyze this issue, the following section focuses on the clinical misdiagnoses of BIA-ALCL.

BIA-ALCL is described in the current literature as extremely rare. The lymphoma occurs more frequently in patients with implants that have a coarse texture, and individuals with a positive genetic family history are at increased risk[20]. Similar to silicone type 2, one possible reason for the clinical misdiagnoses of BIA-ALCL is that malignant processes, especially at an early stage, cannot be reliably detected without thorough histopathological examination and are therefore only suspected. Definitive diagnosis of these malignant cases can only be made through detailed histopathological analysis, supported by relevant findings from the patient's history.

Although the presence of a late seroma can serve as a clinical symptom, it is not a specific diagnostic criterion, as it may also occur in other breast parenchymal diseases and, in particular, in local inflammatory conditions.

The extremely rare breast implant-associated squamous cell carcinoma (BIA-SCC) was not observed in this cohort[21]. For ductal carcinoma in situ (DCIS) and invasive adenocarcinoma (non-specific type, NST), the designation "breast implant-associated adenocarcinoma" (BIA-AC) is proposed within this classification. It should be noted, however, that based on the available data, it was not possible to distinguish between a recurrence and a potentially newly developed secondary carcinoma.

Possible detection of bacterial infections in the context of the classification proposal

Bacterial infections as a complication of silicone breast implants are, in contrast to peri-implant joint infections, very rare[22,23]. Although bacterial colonization of implants and the resulting fibrosis have been extensively described in the literature[24–26], no bacterial infection was detected in any of the 150 peri-implant breast tissue samples in the present dataset. However, if histopathological criteria of infection were observed in a sample[4,27], the finding "suspected infection" could be added and characterized histopathologically. It should be emphasized that, in principle, only microbiological diagnostics—in addition to histopathology—can provide a definitive diagnosis of infection.

Silicone detection using Oil Red O staining in silicone type 2

Using Oil Red O staining, an intense orange reactivity was observed in the form of irregular, partly filamentous, but predominantly granular structures, with the staining mostly detectable at the periphery of silicone vacuoles. This pattern induced by Oil Red O staining has previously only been described in a similar way in a biopsy-based case report[18] and represents a novel finding that is practicable for routine diagnostics. Unlike the polyethylene particles used in endoprosthetics[6], Oil Red O produces an incomplete staining pattern for silicone, as parts of

the silicone appear to be removed during tissue processing. This newly adapted staining method, which was originally developed mainly for the specific detection of polyethylene, now allows a technically rapid and specific detection of silicone and is therefore proposed for the evaluation of capsule tissue in silicone breast implants. It should be noted that intracellular lipids, in particular, can also produce a positive signal. The surface plastic material used in silicone breast implants for fixation purposes ("mesh," sometimes partially resorbable and mostly strongly POL-positive) was not considered in this analysis, as it represents non-silicone implant material.

Conclusions

The PBI classification presented here is based, for the first time, on a systematic histopathological analysis and typification of the three most common breast implant-associated pathologies. The interobserver and intraobserver reliability showed a high to perfect agreement, which adds to the robustness and reproducibility of this classification. It can make a significant contribution to standardized and reproducible histopathological diagnostics. This is highlighted by the considerable discrepancy between clinical and histopathological assessments for silicone type 2 and malignancy type 3, emphasizing the fundamental role of histopathology as the gold standard for diagnosing breast implant-associated pathologies. Since peri-implant silicone leakage can be associated with local fibrotic and inflammatory reactions, the detection of silicone should lead to classification as silicone type 2. Using oblique illumination and the newly adapted, significantly time-saving Oil Red O staining, a specific detection of silicone is possible. For malignancy type 3, none of the four cases would have been diagnosed as malignant without histopathological assessment, underlining the necessity of histopathological diagnostics and typification in this context. The proposed classification, based on straightforward and easily implementable techniques, can enhance practical diagnostic reliability in routine diagnostics—both through the histopathological detection of silicone and by indicating the very rare and often difficult-to-diagnose entities, particularly BIA-ALCL.

Limitations

The study was conducted as a retrospective multicenter analysis, therefore it was not possible to ensure the standardization of the clinical documentation. There is a given heterogeneity in data collection for parameters such as silicone implant types, implantation durations, and data on clinical stages. This should be considered in the interpretation of the sensitivity of the clinical diagnosis. In regard to the small sample size of only 4 malignancy cases, the results should be considered indicative until studies with a larger sample are conducted. Based on this first histopathological typification proposal, future studies should correlate the histopathological types with clinical and radiological data in order to clarify their diagnostic and therapeutic significance.

Practitioner points

- A new reliable classification for the diagnosis of implant pathologies, which provides the basis for pathogenesis and is intended to increase understanding and awareness in the clinical field.
- The classification of peri-implant capsular tissue as a basis for subsequent treatment.
- A newly adapted and readily applicable Oil Red O staining enables the direct and time shortened detection of silicone

Data availability

The Oil Red O staining protocol is available within the supplementary material. The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

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Author contributions

E.K. and M.O. conceived and designed the study. E.K. and F.B.H carried out the data curation. J.R., S.J. L.B. and M.O. collected the data. M.L conceived the statistical design and assisted with data analysis. E.K., F.B.H and M.L analyzed and interpreted the data. E.K. and L.B. drafted the manuscript and prepared the figures and the table. M.O., L.B. and M.K critically revised the manuscript. All authors discussed the results, contributed to the final manuscript, and approved the submitted version.

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Declarations

Competing interests

The authors declare no competing interests.

Additional information

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