




Material Analysis of Explanted Calcified Silicone Intraocular Lenses in Association with Asteroid Hyalosis

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ABSTRACT

Introduction: The aim of this study was to analyze posterior surface opacification in explanted silicone intraocular lenses (IOLs) with clinicopathologic correlation to asteroid hyalosis.

Methods: In a laboratory setup, 12 explanted silicone IOLs underwent laboratory analyses, including light microscopy, scanning electron microscopy (SEM), and energy-dispersive X-ray spectroscopy for elemental composition (EDX). Relevant clinical data were obtained for each case, including gender, age at IOL implantation, dates of implantation and explantation, as well

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as history of neodymium-doped yttrium aluminum garnet (Nd:YAG) laser treatments or other opacification removal attempts. High-resolution optical coherence tomography (OCT) images were obtained in vitro with an anterior segment OCT device (Anterior, Heidelberg Engineering, Heidelberg, Germany).

Results: Calcification located at the posterior optic surface of each lens was identified through SEM and EDX analyses, revealing deposits composed of hydroxyapatite. In all cases, IOL polishing using Nd:YAG laser had been attempted prior to IOL exchange. The clinical functional data showed that this type of IOL opacity led to increase in straylight and subjective symptoms of glare.

Conclusions: Silicone IOLs can develop posterior surface calcification in eyes with asteroid hyalosis. There are mechanical techniques of cleaning the IOL surface but in many cases, IOL explantation is the only sustainable way to reduce the patients' straylight levels and glare symptoms. Due to the risk of posterior surface calcification, silicone IOL implantation should be avoided in eyes with asteroid hyalosis.

Keywords: Asteroid hyalosis; IOL opacification; IOL pathology; Silicone IOLs; IOL calcification

Key Summary Points

Why carry out this study?

Asteroid hyalosis can lead to opacification of the posterior surface of silicone intraocular lenses (IOLs) (secondary IOL calcification).

In this laboratory study, we analyzed a series of cases with posterior surface silicone IOL opacification to improve the understanding of this material change.

What was learned from the study?

The analysis for elemental composition revealed calcium and phosphorus as the main components of the opacification.

Clinicians should avoid implanting silicone IOLs in eyes with asteroid hyalosis, as it could lead to posterior surface IOL calcification elevating intraocular straylight and thereby glare.

INTRODUCTION

Opacification of the intraocular lens (IOL) is a rare, well-known postoperative complication following cataract surgery.¹ It may not obligatorily lead to significantly decreased visual acuity, but may induce increased straylight, leading to reduced quality of vision and glare [2]. A variety of reports described postoperative calcification of hydrophilic acrylic IOLs, with calcification occurring both on the anterior and posterior surfaces of the IOL as well as within the IOL subsurface [1, 3–5]. IOL calcification can usually be confirmed histologically, using standard staining methods like Alizarin Red [1]. The opacification of the silicone intraocular lenses was first shown in 2004 in case reports by Wackernagel et al. and Foot et al. [6, 7]. Its incidence is rare; as of now, only 32 cases have been described [6–18]. Despite the fact that IOLs

made of silicone were more commonly utilized in the past than they are today, some modern IOLs, such as the light-adjustable lens (LAL), are composed of silicone [19, 20]. In contrast to hydrophilic acrylic IOL opacification, this type of opacification is only seen on the posterior surface of the lens and seems to be uniquely associated with asteroid hyalosis. This opacification is characterized by progressive accumulation of white granular or fleck-like deposits that might lead to decreased visual acuity and increased glare [18]. According to the classification of IOL calcification proposed by Neuhann et al., this type of IOL opacification is defined as secondary calcification [21]. In most of the reported cases, different removal attempts have been described to clear the posterior lens surface [12–15, 17]. However, in many cases, the deposits recurred after the treatment, necessitating IOL explantation [6, 8, 9, 11, 17]. Due to the low prevalence of asteroid hyalosis, which ranges from 0.8 to 2.0% [22–24], cases presenting for cataract surgery in clinical routine require special attention.

In this study, we aimed to analyze posterior surface opacification of 12 silicone IOLs that had been explanted and sent to our laboratory and with accompanying case-related clinical data.

METHODS

Intraocular Lens Explants

Twelve IOLs had been explanted from eyes with asteroid hyalosis due to clinically significant opacities between March 2007 and April 2021 and were sent to our laboratory for analysis. For each IOL, information including gender, age of the patient at IOL implantation, dates of implantation and explantation, as well as history of neodymium-doped yttrium aluminum garnet (Nd:YAG) laser treatments or other opacification removal attempts was provided by the explanting surgeon.

Light Microscopy

On receipt of the lenses, photos were made of each IOL using a digital camera (C-7070; Olympus Optical Co Ltd.) and these images were examined using a light microscope (BX50; Olympus Optical Co Ltd, Tokyo, Japan).

Scanning Electron Microscopy and Energy-Dispersive X-Ray Spectroscopy

One half of each silicone IOL was further examined using scanning electron microscopy (SEM) as well as energy-dispersive X-ray spectroscopy (EDX) for elemental composition. The IOL was clamped onto a SEM specimen holder and the surface was examined. Thereafter, the sample was rotated and the other side of the IOL was analyzed in the SEM. The EDX measurements of the surfaces were carried out at an acceleration voltage of 12 kV. To confirm that the IOL material contains silicon, the entire IOL was measured in the SEM using EDX. However, EDX examinations on the bulk IOL cause extreme charging of the specimen, resulting in sample drift and mislocation of the electron beam. To overcome these problems, another preparation was required for the EDX measurements made, a so-called “replica”. For this, the surface of the IOL was pressed onto an adhesive surface and then again removed to leave a layer of superficial incrustations sticking to the (conductive) adhesive, which can be then investigated. After these examinations were completed, the IOL was dissected in an ultramicrotome with a diamond knife. Since the IOL silicone material is extremely soft, cutting the thin section was challenging. The microtomy was performed at low temperatures, where the sample temperature was maintained at $-160\text{ }^{\circ}\text{C}$ and the knife temperature was $-30\text{ }^{\circ}\text{C}$. The sections were then transferred from the water-dimethyl sulfoxide surface to be mounted on a silicon wafer, allowing the EDX measurements to be performed.

Anterior Imaging

In a recent study, we introduced the method of visualizing IOL pathologies using a clinical anterior segment optical coherence tomography (OCT) device, the Anterior (Heidelberg Engineering, Heidelberg, Germany) [25]. The device is used in clinical routine, and we adapted it for studying in vitro opacification of IOLs by building an IOL holder. This holder keeps the lens specimen in an artificial eye with a glass window and an artificial anterior chamber filled with distilled water. In order to demonstrate the posterior surface opacification of the silicone IOL, a vertical high-resolution B-scan cross-section with a length of 7.0 mm was obtained through the center of the IOL using the Anterior device’s Imaging App.

Compliance with Ethics

The patient, showcased as a representative clinical case, provided written informed consent to participate in this study. The collection of patient’s data was registered in the German Clinical Register (Deutsches Register Klinischer Studien) under the reference number DRKS00007837 and was approved by the local Ethics Committee of the University of Heidelberg.

RESULTS

The study IOLs were explanted at the mean age of 78 years. Table 1 contains case-related clinical information about the studied silicone IOLs. In all cases, the IOL was explanted due to opacification with assumed clinical significance. The mean time in the eye was 11 years. One patient had bilateral asteroid hyalosis with posterior surface IOL opacification in both eyes. In all cases, IOL polishing using Nd:YAG laser had been attempted unsuccessfully, therefore IOL exchange was performed.

In all 12 IOLs, localized posterior opacification was confirmed using light microscopy. Macroscopically, as demonstrated in Fig. 1, all IOLs showed opacification in the optical part of

Table 1 Twelve cases of silicone intraocular lens (IOL) opacification with IOL specifications, patient data, and clinical history

IOL	Implanted IOL (manufacturer)	Power (D)	Patient's age at implantation (years)	Implantation	Explanation	Reason for explantation	Removal attempt
1	Clariflex CLRFLXC (IJSV)	5.0	39	Aug 2004	April 2019	Opacification	Nd:YAG laser capsulotomy
2	Clariflex CLRFLXC (IJSV)	21.5	76	June 2006	Jan 2018	Opacification	Nd:YAG laser capsulotomy
3	LI61AO SofPort® (Bausch + Lomb)	25.5	66	March 2007	July 2018	Opacification	Nd:YAG laser capsulotomy
4	Clariflex CLRFLXC (IJSV)	n.k.	75	Oct 2007	Aug 2018	Opacification	Nd:YAG laser capsulotomy
5	CeeOn Edge 911A (IJSV)	16.0	71	Oct 2007	April 2021	Opacification	Nd:YAG laser capsulotomy
6	Clariflex CLRFLXC (IJSV)	22.0	75	Nov 2007	Feb 2016	Opacification	Nd:YAG laser capsulotomy
7	Clariflex CLRFLXC (IJSV)	26.0	65	2008	Dec 2018	Opacification	Nd:YAG laser capsulotomy
8	Z9002 (IJSV)	20.0	62	2008	Jan 2021	Opacification	2x Nd: YAG laser capsulotomy
9	LI61AO SofPort® (Bausch + Lomb)	20.5	70	Feb 2011	Oct 2018	Opacification	5x Nd: YAG laser capsulotomy
10	n.k.	n.k.	n.k.	n.k.	March 2016	Opacification	Nd:YAG laser capsulotomy
11	n.k.	n.k.	n.k.	n.k.	n.k.	Opacification	Nd:YAG laser capsulotomy
12	n.k.	n.k.	n.k.	n.k.	n.k.	Opacification	Nd:YAG laser capsulotomy

The lenses are listed in order of the implantation date

Nd:YAG neodymium-doped yttrium aluminum garnet. D diopter, IOL intraocular lens. n.k. not known

2x stays for 2 times of this treatment, two attempts; *5x* stays for 5 times of this treatment, five attempts)

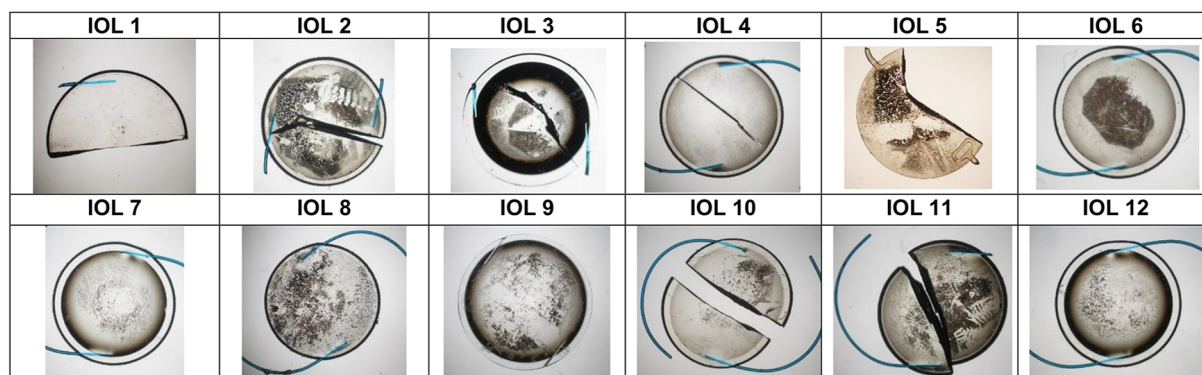


Fig. 1 Light microscopy images representing an overview of the intraocular lens (IOL), higher-magnification images, and scanning electron microscopy of the IOLs 1–12. As

the opacification of the IOL 1 and 4 could partly be removed manually, these IOLs showed partially clear optic parts

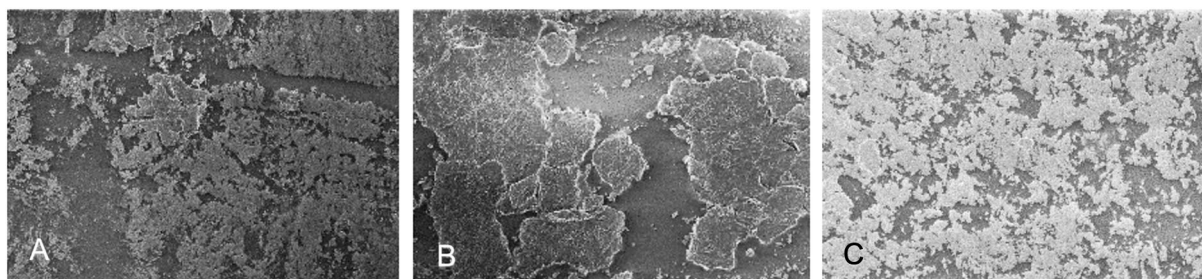


Fig. 2 Scanning electron microscopy of the intraocular lenses (IOLs), demonstrating a crust-like appearance of the deposits. **A** IOL 1. **B** IOL 2. **C** IOL 10

the lens, mostly located in the center and in some cases as well as in the periphery (IOLs 2–5, 7–11). Light microscopy demonstrated numerous and confluent round–ovaloid deposits on the posterior IOL surface. EDX analyses determined that in all cases the lens material is composed of silicone and the opacification of hydroxyapatite. As demonstrated in Fig. 2, SEM of the posterior surface revealed a crust-like appearance of the deposits. EDX analyses demonstrated that the deposits composed of a calcium phosphate and calcification was located at the posterior optic surface of the silicone IOLs. Moreover, the deposit-free area showed the presence of silicon, carbon, and oxygen, which confirms the silicone nature of all analyzed IOLs.

Representative Clinical Case

In December of 2020, a 75-year-old man with asteroid hyalosis presented to our department with decreased and blurred vision for 6 months and an increased glare in the right eye. His medical history was unremarkable, except for chronic bronchitis. Approximately 13 years earlier, the patient underwent uneventful phacoemulsification and implantation of silicone IOLs in both eyes. About 10 years after the surgery, the first signs of the posterior IOL opacification were noted and Nd: YAG laser posterior polishing was attempted on each eye, on the occasion in November 2020. Figure 3 shows anterior segment examination of the patient's right eye from December 2020.

At presentation to our clinic, the patient's corrected distance visual acuity (CDVA) was

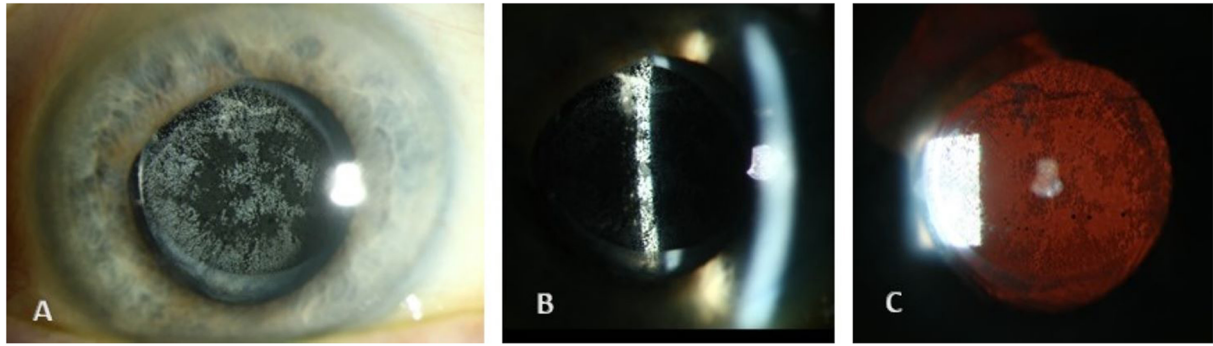


Fig. 3 Anterior segment examination of the patient's right eye from the case report showing diffuse white–grey granular deposits on the posterior surface of the silicone intraocular lens (IOL) in association with asteroid hyalosis. **A** Overview slit-lamp photograph demonstrating IOL opacification and neodymium-doped yttrium aluminum

garnet (Nd:YAG) laser pits on the posterior IOL surface. **B** Direct focal slit examination pointing out the diffuse dissemination of the dense deposits on the IOL surface. **C** Retroillumination photograph showing opacified silicone IOL and posterior capsule opening

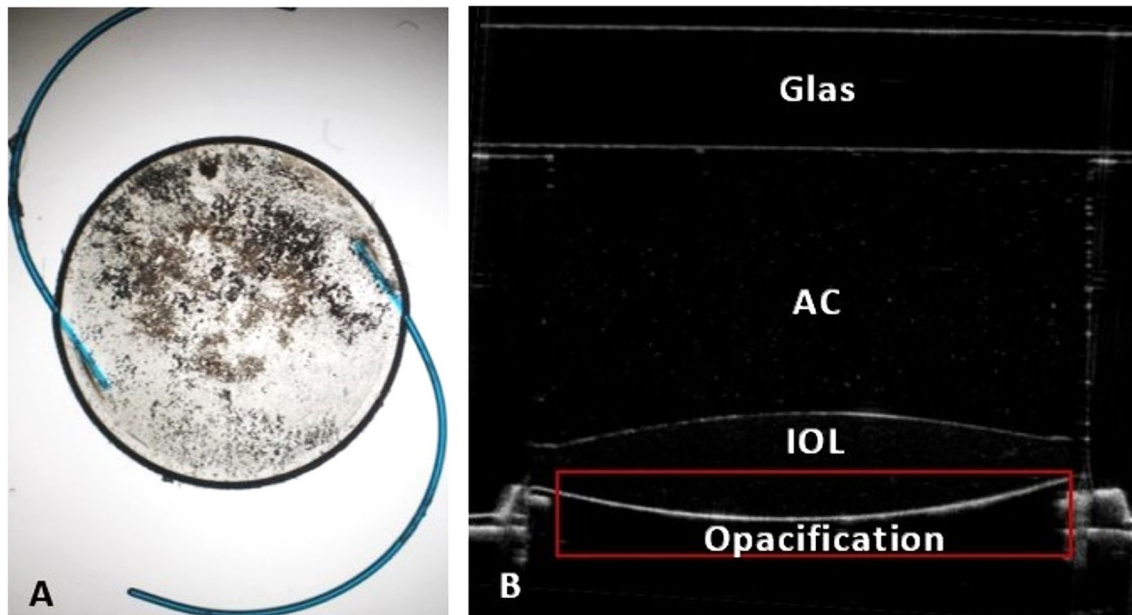


Fig. 4 Silicone intraocular lens (IOL) with posterior surface calcification. **A** Photograph of the explanted IOL with dystrophic opacification. **B** High-resolution optical coherence tomography (OCT) cross-section image of the

IOL from A. The region of the posterior surface opacification is located within the *red rectangle*. *AC* artificial anterior chamber filled with distilled water

0.42 logMAR and intraocular pressure (IOP) was 14 mmHg in the right eye. Straylight was quantified using a straylight meter (C-quant, Oculus, Berlin, Germany), revealing elevated levels in the patient's right eye compared to his

left eye, with 2.20 and 1.45 log(s), respectively. Slit-lamp examination showed white–grey membranous deposits and Nd:YAG pits occluding the posterior capsular opening on the posterior surface of the IOL. The patient

underwent an IOL-exchange at our clinic. An experienced surgeon (G.U.A.) first tried to polish the IOL, which was unsuccessful. The surgeon decided to exchange the lens and implant a sulcus-fixated IOL. After the IOL exchange, the patient's CDVA improved to 0.3 logMAR. To visualize the IOL opacification, the explanted lens was analyzed using high-resolution optical coherence tomography (OCT), which showed the posterior surface IOL opacification (Fig. 4).

DISCUSSION

The association between asteroid hyalosis and silicone IOL opacification was first reported in 2004. Since then, there have been only a few cases (cumulative 32) of silicone IOLs of different designs presented in the literature [6–18]. The presented cases are the largest series of this material change and improve the understanding of secondary silicone IOL calcification, which facilitates clinical decision-making.

Asteroid hyalosis is defined as a benign degenerative condition of the vitreous. Clinically, it presents as round, white-yellow vitreous opacities that can confluence and tend to move with eye movements. The etiology of this rare condition remains unclear, whereas the composition of asteroid hyalosis particles revealed a structure similar to hydroxyapatite. Considering the fact that the prevalence of this condition increases with age, more cases might be expected in the future [26]. Although asteroid hyalosis is usually asymptomatic, it can have an impact on the visual quality by increasing glare and decreasing contrast sensitivity. Regarding cataract surgery, this condition can make the procedure more challenging, as it might cause problems in obtaining valid refraction and axial length measurements [27]. Furthermore, the presence of asteroid hyalosis may lead to difficulties during cataract surgery, as it complicates the evaluation of the posterior capsule [26].

Silicone IOL implantation in eyes with asteroid hyalosis can lead to posterior surface opacification, which can be diagnosed upon slit-lamp examination. However, this condition may imitate posterior capsular opacification (PCO), and therefore it might be difficult to

differentiate the correct localization of the opacification [11].

In this laboratory study, we analyzed posterior surface silicone IOL opacification and confirmed that the opacity was due to calcification. The material accumulating on the posterior surface is likely to derive from the asteroid bodies or from a similar process that leads to the asteroid body formation itself [17]. The analysis for elemental composition revealed calcium and phosphorus as the main components of the opacification, which corresponds to the results in previous analyses [9].

A variety of removal attempts has been reported since the first introduction of the association between the asteroid hyalosis and posterior surface silicone IOL opacification, including Nd:YAG laser and techniques via pars plana vitrectomy (PPV) [8, 12, 13, 15, 17, 28]. Foot et al. and Wackernagel et al. reported about cleaning the IOL surface with Nd:YAG laser. However, the deposits reaccumulated, requiring then explantation of the IOL [6, 7]. On the contrary, Mehta et al. described a successful approach of cleaning the IOL surface using PPV. However, most of the cases revealed different results with incomplete removal of the opacification [14, 15]. Accordingly, in all cases of our study, there were initial attempts of IOL polishing using a Nd:YAG laser. However, the opacification remained or reappeared, and patients underwent IOL exchange. In particular, case 9 underwent five Nd:YAG laser treatments prior to IOL explantation. The opened posterior capsule may lead to challenges: first, an open posterior capsule might complicate a future IOL exchange. Furthermore, the direct contact between the IOL and vitreous might increase the risk for additional calcification [9]. However, despite the barrier nature of the posterior capsule, it lets calcium and phosphate (both components of the asteroid hyalosis particles) go through and accumulate even in the presence of an intact posterior capsule [11]. Morphologically, all cases from our study showed a crust-like calcification pattern, which is in accordance with previous studies that detected only this type of pattern in the secondary calcification cases [29].

High-resolution OCT images obtained with an anterior segment OCT verified the surface, not the subsurface nature of this opacification type. Moreover, it enables the differentiation of the localization of the opacification as well as distinguishing it from other reasons for opacification, like PCO, which can be a helpful tool in a clinical setting. The current study showed that in all cases, only surgical IOL exchange improved the visual quality of affected patients. Therefore, the indication for Nd:YAG laser treatment should be made with caution, as an open posterior capsule complicates IOL exchange and does not solve the problem in the long run.

It is worth noting that opacification develops in silicone IOLs in eyes with asteroid hyalosis but not in acrylic IOLs. We suggest a chemical explanation for this difference: in the Si–O–Si bond, the oxygen atom is more electronegative and can therefore bind Ca²⁺ better and more firmly than in a C–O–C bond because carbon is more electronegative than Silicon (Si) and draws more electron density from the oxygen atom.

Regarding visual function, former studies showed that the combination of asteroid hyalosis and silicone IOL can lead to a decreased visual acuity as well as glare due to the opacification of the posterior IOL surface. Vlasman et al. analyzed the straylight due to IOL opacification in association with asteroid hyalosis and revealed an 8.2-fold increased straylight level in comparison to healthy eyes [18]. Similarly, in the case presented from our study, the patient suffered from an elevated straylight level as well.

In summary, clinicians should avoid implanting silicone IOLs in eyes with asteroid hyalosis, as it could lead to posterior surface IOL calcification. There are several techniques for cleaning the IOL posterior surface, but in many cases IOL explantation is the best option to sustainably improve the patients' quality of vision. As asteroid hyalosis as well as the silicone IOL opacification could make the surgery challenging, it is important to visualize the anterior segment in such cases.

Medical Writing/Editorial Assistance Donald J. Munro (David J. Apple Center for Vision Research, Department of Ophthalmology, University of Heidelberg, Heidelberg, Germany) contributed to the review of the manuscript.

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Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

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Ethical Approval. The patient demonstrated as representative clinical case gave written informed consent to participate in this study. The collection of patient's data was registered in the German Clinical Register (Deutsches Register Klinischer Studien) under the reference number DRKS00007837 and was approved by the local Ethics Committee of the University of Heidelberg.

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