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## The use of Cerasorb Foam in spinal surgery



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## Cerasorb foam in spinal surgery

### Summary

**Introduction and Purpose:** Bone substitute materials are often used as fusion material to treat bone defects and in spinal surgery. Beta-tricalcium phosphate ( $\beta$ -TCP) is a synthetic product that was used in its Cerasorb Foam variant for the first time during this observational study of patients with lumbar spondylodesis.

**Patients and methods:** A total of 34 patients with indications favouring instrumented lumbar spondylodesis were included in this prospective, non-interventional, open, single-centred medical study. Autogenic bone and Cerasorb foam impregnated with bone marrow (85 percent by weight phase-free  $\beta$ -TCP granulates and 15 percent by weight porcine collagen complex) were used as the fusion material. Clinical and X-Ray checks were made after 3 and 12 months, recording pain intensity and functional impairment, and giving a descriptive account of new bone generation and resorption of the ceramic. In addition to this, the researchers recorded the distances that patients could walk free of pain along with details of any complications.

**Results:** The use of the Cerasorb Foam in the operations was technically straightforward. No complications clearly associated with the fusion material occurred in the case of any patient. The single infected wound requiring revision surgery (2.9 %) was within the expected frequency range. From a clinical point of view, statistically significant improvement in pain intensities and in function were consistently observed after 3 and after 12 months. As time went on, resorption of posterolaterally added bone substitute material accelerated according to radiological evidence, as did generation of new bone.

**Final conclusions:** In the area of lumbar spinal surgery Cerasorb Foam was proven and, in combination with autogenic bone material, was shown to reliably generate bone for spondylodesis. However, further studies will be needed in the future to compare the product in terms of its fusion-promoting properties against other substitute bone materials.

*Key words:*  $\beta$ -TCP, Beta-Tricalcium phosphate, Cerasorb, Cerasorb Foam, Fusion, ceramic bone substitutes, lumbar spinal column, spondylodesis

### Zusammenfassung

**Einleitung und Ziel:** Neben der Behandlung von ossären Defekten werden auch im Bereich der spinalen Chirurgie häufig Knochenersatzstoffe als Fusionsmaterial eingesetzt. Beta-Tricalciumphosphat ( $\beta$ -TCP) ist ein synthetisch hergestelltes keramisches Produkt, das in dieser Beobachtungsstudie bei Patienten mit lumbaler Spondylodese erstmals als Cerasorb-Foam-Variante zur Anwendung kam.

**Patienten und Methode:** Im Rahmen einer prospektiven, nicht interventionellen, offenen, monozentrischen Studie wurden insgesamt 34 Patienten mit Indikation zur instrumentierten lumbalen Spondylodese eingeschlossen. Als Fusionsmaterial kamen autologer Knochen und mit Knochenmark getränktes Cerasorb Foam (85 Gewichts-Prozente phase-reine  $\beta$ -TCP-Granulate und 15 Gewichts-Prozente porciner Kollagen-Komplex) zum Einsatz. Klinische und röntgenologische Kontrollen erfolgten nach 3 und 12 Monaten mit Erhebung der Schmerzintensität und der funktionellen Beeinträchtigungen sowie deskriptiver Beschreibung der Knochenneubildung und der Resorption der Keramik. Zusätzlich wurden die Länge der schmerzfreien Gehstrecke und Komplikationen erfasst.

**Ergebnisse:** Die intraoperative Anwendung des Cerasorb Foam war technisch einfach. Bei keinem der Patienten kam es zu Komplikationen, die mit dem Fusionsmaterial eindeutig zu assoziieren gewesen wären. Eine einzige revisionsbedürftige Wundinfektion lag mit 2,9 % im zu erwartenden Häufigkeitsbereich. Klinisch zeigten sich nach 3 und 12 Monaten stets statistisch signifikante Verbesserungen in Bezug zur Schmerzsituation und dem funktionellen Outcome. Im zeitlichen Verlauf nahmen röntgenologisch die Resorption der posterolateral angelagerten Knochenersatzmaterialanteile und parallel dazu die Knochenneubildung zu.

**Schlussfolgerung:** Als synthetischer Knochenersatzstoff hat sich Cerasorb Foam im Bereich der lumbalen spinalen Chirurgie bewährt und führt in Kombination mit autogenem Knochenmaterial zuverlässig zur Spondylodese. Zukünftige Studien sind aber notwendig, um das Produkt hinsichtlich seiner fusionsfördernden Eigenschaften auch mit anderen Knochenersatzstoffen vergleichen zu können.

*Schlüsselwörter:*  $\beta$ -TCP, Beta-Tricalciumphosphat, Cerasorb, Cerasorb Foam, Fusion, keramischer Knochenersatz, Lendenwirbelsäule, Spondylodese

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**Introduction**

Spondylodesis is a common intervention in spinal surgery carried out most frequently on the lumbar spinal column. To achieve lasting stability for a fusion it is absolutely necessary to achieve an accretion of bone material on the relevant spinal segments, which will generally have been instrumentated. For this purpose, autogenic bone material is preferred, which is generally obtained either by carrying out an additional decompression to harvest corticospongiosa particles, or by making an additional intervention on the iliac crest to harvest chips of tricortical material and/or spongiosa. The osteoconductive, inductive and osteogenic properties the material can thus be employed. If insufficient material is available from the patient's own body, allogenic and xenogenic bone transplants are also available for the augmentation. As an alternative process, a number of bone substitute materials have been developed from synthetic materials. These substitutes exhibit osteoconductive properties. Among such materials are calcium phosphate ceramics, which have been at the centre of research efforts for more than four decades [1]. Such materials are non-toxic, non-immunogenic, non-carcinogenic and non-teratogenic, and exhibit very good biocompatibility. They show a close chemical and crystallographic similarity to bone material [1]. The main variants of the material are Hydroxylapatite (HA) and Tricalcium phosphate ceramics (TCP), which have a high rate of biodegradability. Since  $\alpha$ -TCP ceramics convert into very small HA particles in fluid biological environments and can accumulate in the lymphatic system,  $\beta$ -TCPs lend themselves particularly well to use as a bone-generation material through which the resorption and bone regeneration processes can go on at the same time [1, 2].

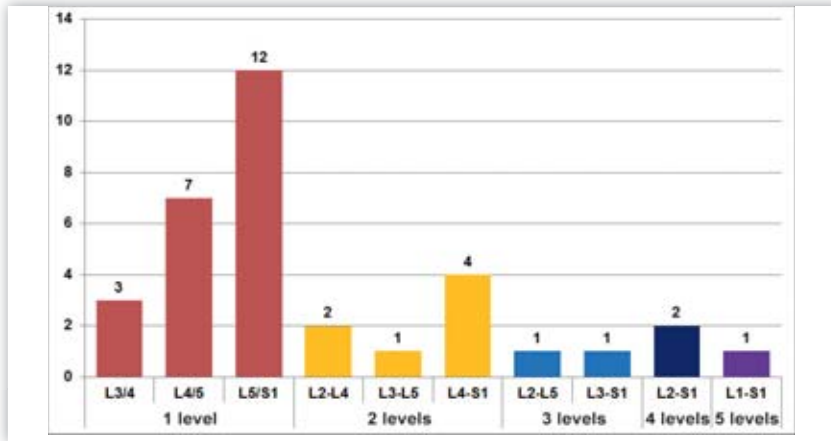
$\beta$ -TCP is used primarily in surgery for accidental injuries, orthopedics and mouth, jaw and face surgery to fill out bone defects. A  $\beta$ -TCP under the brand name „Cerasorb“ has been studied for

Diagnosis	n	%
Osteochondrosis	19	55.9
Spondylolisthesis/Retrolisthesis	13	38.2
Degenerative scoliosis	5	14.7
Post-disectomy syndrome	2	5.9
Spinal stenosis	13	38.2
Spinal disc herniation	1	2.9
Instability after spondylodesis	3	8.8

**Table 1** Pre-operative Diagnoses, multiple responses possible

Cerasorb® Foam	Mouldable	Flexible
Dimensions (length x width by height)/Volume		
25 x 25 x 4 mm/2.5 cm <sup>3</sup>	1	0
50 x 25 x 4 mm/5.0 cm <sup>3</sup>	1	0
100 x 25 x 4 mm/10.0 cm <sup>3</sup>	18	20
<b>Autogenic bones (cm<sup>3</sup>)</b>	<b>n</b>	
1	1	
4	1	
5	16	
10	13	
15	2	
20	1	
<b>Bone marrow aspirate (cm<sup>3</sup>)</b>	<b>n</b>	
5	10	
10	19	
15	3	
20	1	
40	1	

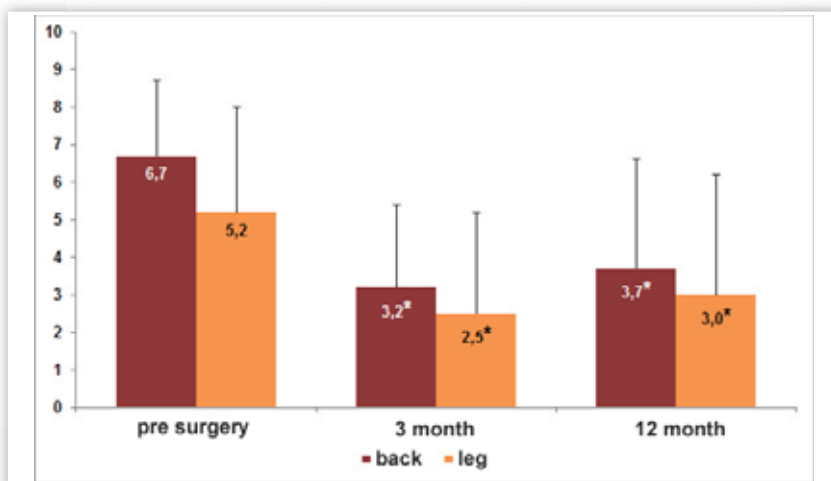
**Table 2** Quantitative data on substances used in spondylodesis, each of 6 patients were treated with 2 pieces of Cerasorb Foam.



**Figure 1** Distribution of fused spinal segments



**Figure 2a–b** Fusion material used: **a)** Cerasorb Foam cut into strips, some soaked in bone marrow aspirate, **b)** Cerasorb Foam impregnated with bone marrow aspirate and additionally mixed with autogenic bone fragments.



**Figure 3** Pain intensity using a VAS scale for back and leg pain during the postoperative period. \* Shows a statistically significant difference to the initial pre-operative value.

terial is used mainly as a fusion bulking material to augment autogenic bones. The benefits of the use of  $\beta$ -TCP as a foam as opposed to as a granulate is its malleability and the ceramic particles ability to bond firmly to the collagen matrix. While up until now only Breil-Wirth and Jerosch have reported clinical experience in the use of  $\beta$ -TCP as a foam (in the form of „Cerasorb Ortho Foam“) in surgery on the limbs, to the best of the authors’ knowledge, no papers have been published on the use of the same product in the field of spinal surgery [5, 6]. For this reason, we would like to present the initial results from a prospective single-centre observational study of patients undergoing lumbar spondylodesis.

**Patients and methods**

As part of a prospective non-interventional, open, single-centre study approved by the relevant local ethical committee (Vote no. 6436 on 06/06/2013) a total of 34 patients were included and evaluated for a period of two years (from 07/2013 to 06/2015). All patients gave a full written declaration of consent to participate. 25 of the subjects were female (73.5 %) and the other 9 male (26.5 %). Their average age was 58.3 years (ranging from 20 to 79). Their mean body weight was 79.3 kg (with a range of between 55 and 111 kg) and their mean body height was 166.0 cm (ranging from 148 to 196 cm). The most commonly reported co-morbidities were the following: arterial hypertension (10 cases), Diabetes mellitus (6 cases), chronic obstructive lung ailments and coronary heart disease (4 cases of each). Eight patients (23,5 %) reported nicotine abuse. In the case of one participant, an autoimmune disease or calcium metabolic ailment was reported. Criteria for inclusion in the study were the presence of degenerative and/or instability-related ailments of the lumbar column giving indications for the execution of a spondylodesis procedure due to persistent problems despite exhaustion more conservative therapies over a period of at least six months. The diagnoses can be seen in Table 1. The most common situation was one involving an operation on the lower lumbar area (L4/5 and L5/S1) (Fig. 1). In 22 cases, a single segment was in-

use in dental medicine in particular, giving similar results to endogenous bone [3]. The substance is available in the

form of granulates, moulded pieces, as a paste, and even as a flexible and mouldable foam [4]. In the spinal area, the ma-

cluded in the fusion, in 7 more cases two vertebrae were included, while in 3 cases 3 vertebrae were involved, in two cases four and in one case five. A total of 55 vertebrae were reinforced in all.

## Operation

All spondylodesis were carried out dorsally either as PLFs (posterolumbar fusions – 4 times), PLIFs or TLIFs (postero- or transforamial lumbar interbody fusions – 27 times) or using a combination of the two procedures in the case of multi-vertebra interventions (3 times). In one case of a spinal canal stenosis, all compressed neural structures were relieved through the use of interlaminar windows, hemilaminectomies or full laminectomies.

Implants included 2 polyaxial pedicle screw-rod systems (XIA, Stryker GmbH & Co. KG, Duisburg; Solera, Medtronic GmbH, Meerbusch) and, in the case of a PLIF or TLIF procedures, cages made of PEEK (Polyether ether ketone) (OIC TL, Stryker GmbH & Co. KG, Duisburg; Crescent, Medtronic GmbH, Meerbusch), which were positioned in an interbody position. In all interventions, the facet joints of the relevant segments had cartilage removed and the vertebrae were decorticated. Vertebrae that remained intact were also trimmed. In order to facilitate spondylodesis, autogenic bone material released by the decompression process was used in shredded form, freed of soft tissues. It was mixed with swabs of Cerasorb Flexible Foam cut into strips and Cerasorb Mouldable Foam (curasan AG, Kleinstheim) (see Fig 2. Tab. 2). Both types of foam are a highly porous synthetic composite made up of porcine collagen complex (15 percent by weight) and phase-free  $\beta$ -TCP granulates (85 percent by weight). Cerasorb Foam in its „Mouldable“ form is kneadable and shapeable, and has a low density. The „Flexible“ form of the product is highly elastic and has a higher density [7]. The foam material was always soaked in bone marrow aspirate obtained after opening the pedicle and before inserting the screws (Tab. 2). This mixture of autogenic bone, Cerasorb Foam and bone marrow aspirate was always (posterolaterally) added to the transverse processes, as well as interbodily in the case of a PLIF and TLIF,

and dorsally for the parts of the vertebral arch left intact. No augmentation using allogenic or xenogenic bone material or BMP (bone morphogenetic protein) was carried out.

## Clinical data

All patients received a questionnaire before the intervention and both 3 and 12 months after it and were asked to fill it out. The questionnaire asked them to use a visual analogue scale (VAS) to measure pain intensity and to assess functional impairment using the Oswestry Disability Index (ODI) and the Roland-Morris Disability Questionnaire (RM). In addition, they were asked to indicate the distance they could walk free of pain. Finally, any complications that emerged in the course of post-operative recovery were recorded.

## Radiological assessment

The radiological checks were made exclusively using X-Rays of the lumbar spinal region using two views (AP and lateral) without any contrast media both directly after the intervention and 3 and 12 months later. The X-ray assessment involved a purely descriptive evaluation of formation of new bone (classified into complete; pronounced; moderate; slight; none) and resorption of Cerasorb (complete; partial; no visible change) on the basis of the AP images taken at 3 and 12 months after the intervention, in a process in which the posterolateral spondylodesis brace was considered and classified in terms of the two above-described parameters. The evaluation of resorption of the  $\beta$ -TCP is made possible by the fact that the ceramic contents of the foam remain strongly echogenic and through their osteoconductive effect and progressive resorption and conversion into bone become progressively less visible to X-rays as time goes on.

## Statistical analysis

The data obtained from the questionnaire (VAS, ODI, RM) have been assessed for statistically significant differences with the T-Test for paired samples with a level of significance of  $p < 0.05$ .

## Results

It was possible to evaluate 32 of the 34 patients clinically and radiologically 3 months after their interventions, while 31 of them could be evaluated after 12 months.

## Questionnaire

The evolution of pain intensity on the basis of VAS for the patients' back and leg during the postoperative period is shown in Fig. 3. The statistically significant reduction both after 3 and after 12 months can be clearly seen. The results for ODI and RM are shown graphically in Fig. 4, again showing a statistically significant improvement in the data on functional impairment as compared to the point in time immediately after the operation.

## Walking distance

Walking distance was limited to an average of 423 m (ranging from 15 to 1000 m) for 30 of the 34 patients. 3 months later, 25 patients reported a pain-induced restriction on walking distance to an average of 618 m (ranging from 50 to 1000 m) and after 12 months to an average of 990 m (50 to 3000 m).

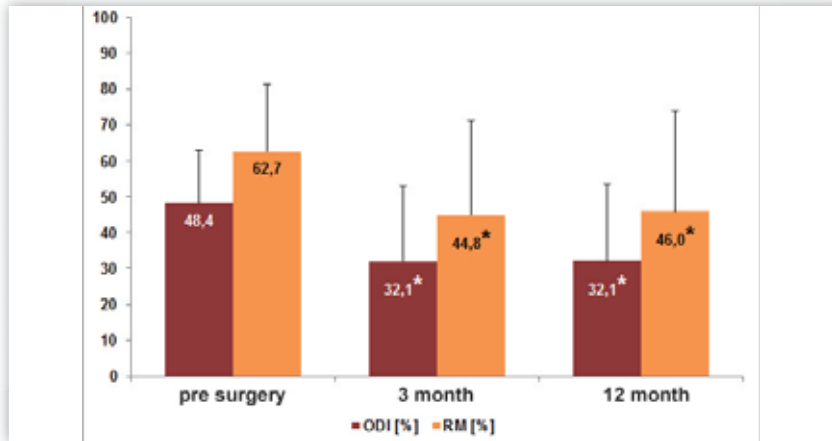
## Complications

While no problems were encountered during the intervention, 2 patients presented complications early in the postoperative period that required renewed surgery (these complications were one case of cage dislocation and an infected haematoma). A third (female) participant developed a deep-vein thrombosis of the leg a few days after the intervention. In the case of one further patient, it was detected via X-ray imaging during the 12-month check that a pedicle screw had come loose. During the consequent intervention to remove the metal, no evidence was found of pseudarthrosis.

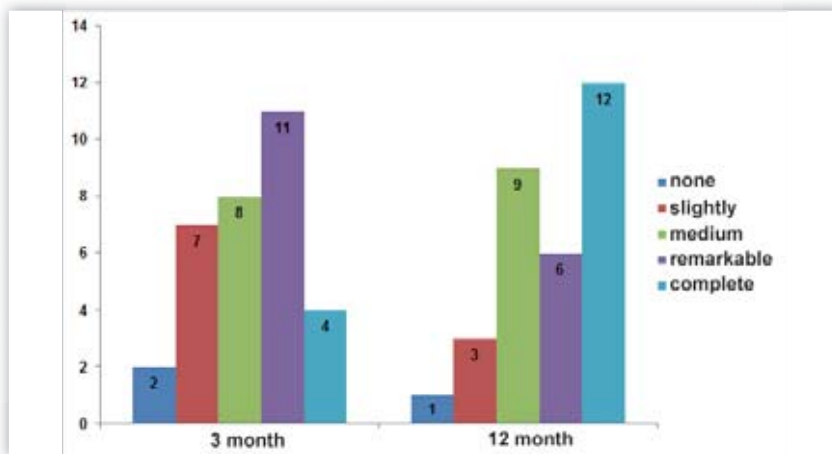
## Radiological assessment

You can see the posterolateral bone regeneration after 3 and after 12 months in Figure 5 and resorption of the ceramic material in Figure 6. It can be seen that the synthetic bone substitute material

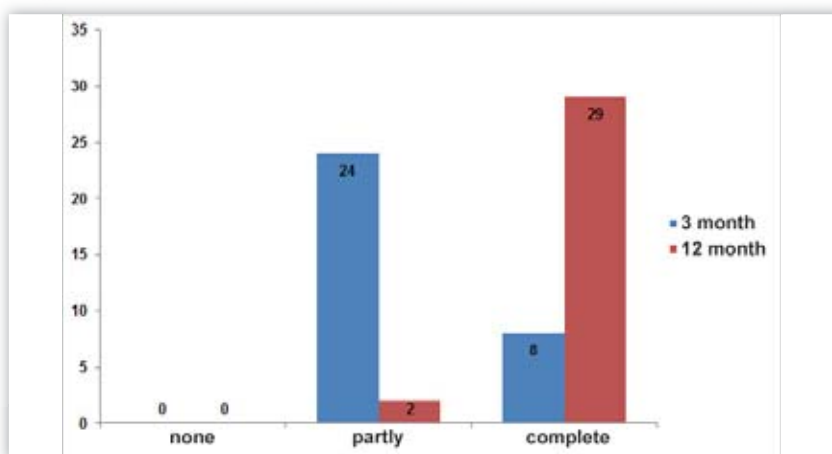




**Figure 4** Functional impairment using the ODI and RM scales during the postoperative period. \* Shows a statistically significant difference to the initial pre-operative value.



**Figure 5** Posterolateral bone regeneration after 3 months and after 12 months



**Figure 6** Resorption of ceramic material after 3 months and after 12 months

becomes progressively less visible as time goes on, indicating increased resorption, and that the rate of fusion increases parallel to this process (Fig. 7).

**Discussion**

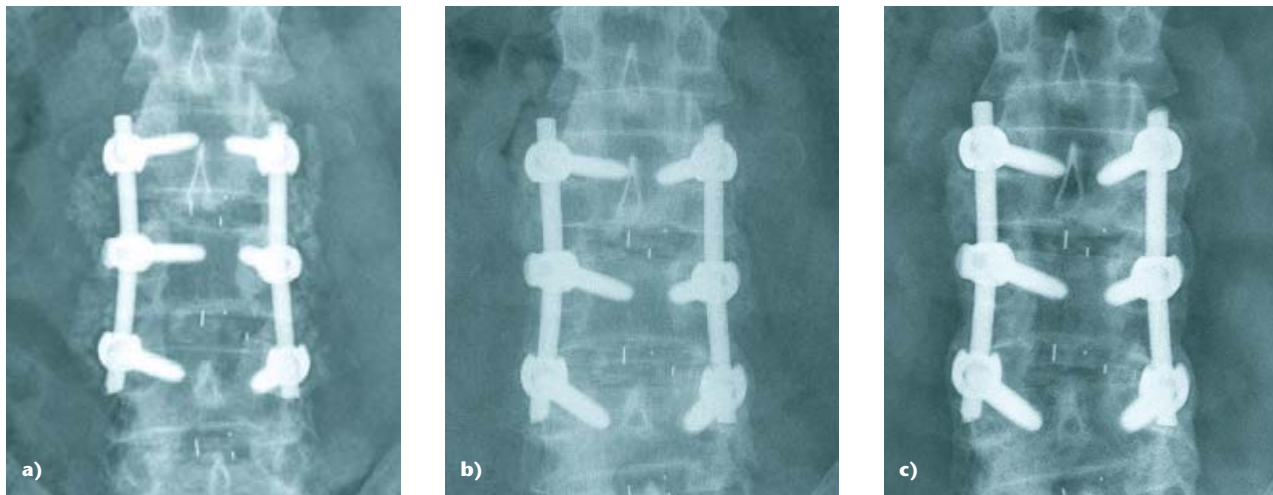
For a long time now, autogenic bone from the pelvic crest has been consider-

ed the gold standard material for use in the spine to achieve spondylosis. Using this material, a fusion rate of up to 98.9 % has been achieved in the case of PLIF procedures [8]. However, drawbacks of the method include donor site morbidity causing pain and possible complications, as well as issues of restricted availability [9]. These drawbacks provided the motivation to search for alternative materials that enable fusion in a similar manner to the effect of bones taken from the patient’s own body and/or that are likely to encourage fusion when used in combination with autogenic bones.  $\beta$ -TCP is a synthetic product designed for these purposes. It is available in a number of different compositions and presentations [10]. Where bone marrow aspirate is added to the ceramic, the osteoconductive properties of the material combine with the osteogenic capacity of bone marrow.

A number of clinical studies have shown that the use of  $\beta$ -TCP together with autogenic bone have provided a fusion rate high enough to achieve a PLF success rate of between 85% and 100% [10–15].

Up until now only 2 surveys have been published on the use of  $\beta$ -TCP in its Cerasorb Foam variant in the composition identical to that used in the present observational study (85 percent by weight of phase-free  $\beta$ -TCP granulates and 15 percent by weight of porcine collagen complex) for filling out bone defects. In these studies, the product has been proven on an animal model to be a very suitable substitute for bone material, showing a high level of osteoconductivity and biocompatibility [16, 17].

However, as far as the authors are aware, the series of clinical cases presented here is the first that reports experiences in the use of  $\beta$ -TCP Cerasorb in foam form for use as a fusion material on the lumbar spinal column. The two variant products (i.e. „Flexible and „Mouldable“) were found to show good manageability, as the foam could be easily broken up and cut into thin strips both before and after soaking with bone marrow aspirate. It was also possible to place the ceramic swabs mixed with autogenic bone particles on the transverse processes or in the intervertebral disc area without encountering problems. There was no clinical indication of any intolerance. The single isolated case of an in-



**Figure 7a-c** sample case of a TLIF L2/3 and L3/4 was supplemented with autogenic bone material mixed with Cerasorb Foam on both sides of L2-4. **a)** Direct postoperative check showing clear signs of the ceramic portion of the bone substitute material  $\beta$ -TCP, **b)** Control at 3 months with full resorption and pronounced bone regeneration, **c)** Control at 12 months showing complete bone regeneration.

ected wound in the series, which was most likely caused by an infected haematoma, yields an infection frequency of 2.9%, putting it at the lower end of the frequency scale, which is given in the literature as between 0.7% and 11.9% [18–20]. Neither of the other complications (one case of thrombosis and one of cage dislocation) could be attributed to the fusion material used. In addition, in the single case of a pedicle screw coming loose, pseudarthrosis could be ruled out intraoperatively by virtue of the evidence that fusion was robust.

The behaviour of Cerasorb Foam in terms of resorption and its bone regeneration properties was evaluated in a purely descriptive manner in this observational study through the use of X-ray imaging of the lumbar spinal column. The authors are aware of the restricted informational value of this method, since in order to attain a more precise fix on fusion one would need either computer tomography or functional X-Ray images to evaluate stability. The only technique available to firmly rule out – or possibly indicate – the presence of pseudarthrosis is provided by the removal of implanted metal accompanied by an intraoperative check on the spondylodesis join for stability, a procedure that is now indicated only for well-founded reasons in individual cases. Despite this limi-

tation, the data actually collected give clear evidence of the properties of the synthetic ceramic material over time. Thus a partial resorption of the  $\beta$ -TCP, which was highly visible on the initial X-ray images, was reported after 3 months among 24 patients (75.0 %), with full resorption within the same period in 8 cases (25.0 %). After 12 months, ceramic residues were visible by X-ray in 2 cases (6.5 %), while for all the 29 remaining patients (93.5 %) no such remnants were present. In parallel with this, new posterolateral bone generation increased continuously during observation period on the lumbar spinal column that was operated on. As early as 3 months after the intervention a majority of patients showed either moderate ( $n = 8$ , 25 %) or pronounced new bone generation ( $n = 11$ , 34.4 %) While after 3 months this process was characterised as complete for 4 patients (12.5 %) and it was characterised as complete for 12 participants (38.7 %) after 12 months, it was evaluated as pronounced in 6 cases (19.4 %) and as moderate for 9 patients (29.0 %). In this context it must be remarked that, where an exclusively descriptive account of a posterolateral bone consolidation independent of the fusion material applied during the operation is observed regularly, this consolidation will become less and less discernable through the use of X-rays as time goes

on after the intervention. However, this phenomenon should not be considered a sign of pseudarthrosis, and no clear correlation with the clinical findings appears to exist [21].

In relation to changes in intensity of pain, statistically significant reductions were observed for both back and leg pain during both post operative checks, with reduction in the pain level to about half of the initial values in each case. Results for the evolution of functional impairment, as measured by ODI and RM, were similar. In this area statistically significant levels of impairment could be observed consistently after 3 and 12 months, though the changes were not as clearly detectable as in the case of pain measurements. In interpreting these data, the relatively small number of cases included in this observational study should be considered a limiting factor. In addition to this, it should be observed that it is not alone the selection of fusion material that is decisive, but rather a variety of different factors (e.g. operating indications, underlying pathologies, the initial clinical situation, psycho-social conditions) are responsible for outcomes. Not least there is the fact that there is no strong relationship between the extent of fusion in a lumbar spondylodesis and clinical findings [21].

Also to be considered a limitation on the design selected for the study is that

the absence of a control group means – in relation to the radiological results in particular – that there can be no direct comparison with other fusion materials, for example. Future studies should therefore follow an approach that allows the further analysis of the behaviour of the  $\beta$ -TCP substance in comparison with other materials, such as autogenous and allogenic bone material and in particular other bone substitute materials that may provide an alternative to Cerasorb Foam.

### Final conclusions

On the basis of the knowledge gained from this observational study, the use of the  $\beta$ -TCP synthetic ceramic bone substitute material in its Cerasorb Foam

variant with the addition of bone marrow aspirate has been shown to be very suitable for achieving an augmentation of autogenic bone material in lumbar spondylodesis. However, further studies will be needed in the future in order to compare the product in terms of its fusion promoting properties against other substitute bone materials. **OUP**

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**Conflicts of interest:** D. Daentzer has reported no conflict of interest. W.D. Hübner is a staff researcher at curasan AG.

**Ethics Committee:** This study was approved by the local ethics committee (by vote at the Hanover Medical School on 06/06/2013, Vote No. 6436).

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