Orthogem TriPore® HA: 11 to 12 Year Post Surgery Clinical Follow-up

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Background

- TriPore HA is a unique formulation of hydroxyapatite and is the first bone graft substitute of its kind to show reliable resorption in lumbar spine fusion procedures.
- The novel TriPore HA structure consists of macropores, midipores [1, 2] and microspaces. The structure allows early population of the graft by osteocytes, not only inside the connecting macropores but also within the ceramic body. [1, 2]
- The first clinical trial to evaluate the use of TriPore in humans was conducted in 10 subjects in 2007-8. Nine (9) of the 10 subjects enrolled demonstrated successful clinical and radiographical outcomes that showed evidence of fusion 12 months post surgery.[1]
- The current data represents the longitudinal qualitative and radiological assessments for 7 of the 10 original participants, 10+ years after surgery.

Objectives

To assess the following outcomes at 10+ years post surgery:

- Evidence of fusion utilizing plain x-rays.
- Overall health status, pain, lower back function and satisfaction with the treatment utilizing : Euro-QOL 5 Dimension score (EQ5D-5L)
- Oswestry Low Back Disability Questionnaire (ODI), a Back and Leg Pain Visual Analog Scale (VAS) and the NASS Patient Satisfaction Evaluation (PSE)

Participants

- The follow up study group consisted of 7 subjects.
- Out of the original group of 10 participants only Subject 3 was deemed a clinical failure at 12 months post surgery.
- Table 1 outlines the characteristics of the patients that participated in the longitudinal evaluation.

Table 1: Subject Characteristics

Subject	Gender	Age	Follow Up Time	Fusion; Procedure
1	F	76	12 y 2 m	L4-S1; TLIF
2	F	65	11 y 3 m	L4/5; PLF
3	F	60	12 y	L2-L4; PLF (no screws)
4	F	64	11 y 4 m	L4/5; PLF
5	F	52	12 y	L4/5; F&B fusion L5/S1; TDR
6	M	63	12 y 2 m	L3-S1; TLIF
7	F	73	12 y 1 m	Revisions L2-L5; PLF

Methods and Results

Methods: Seven (7) of the 10 subjects that participated in the initial clinical trial that evaluated the efficacy of TriPore consented to long term follow up assessments. Subjects in this cohort had lumbar spine weight-bearing X-rays and completed self assessment questionnaires and scales. The timeframe of the assessment was relative to the date of surgery and listed in **Table 1.**

Questionnaire Results:

- **EQ5D-5L:** 6 of 7 subjects experienced no or slight problems in the domains of Self-Care and none complained of Anxiety/Depression. Three experienced severe problems in the areas of Usual Activities (1) and Pain (2) of which one was the subject failure. The distribution of scores is outlined in **Table 2.**
- The mean EQ5D Health State score was 69/100 (range: 30-95) where 100 = Best Health and 0= Worst Health. 4 of 7 subjects rated themselves as 75 or higher and 1 subject's self rating was a 30 (initial clinical failure). The mean score represents a positive outlook on overall health.
- **ODI:** The median ODI score was 20% (range: 0-58%). The majority of subjects scores reflected minimal disability (4) or moderate disability (2). The subject deemed an initial failure was rated as having severe disability.
- **VAS Pain:** Subjects rated their pain on a scale of 0-10 (0 = No Pain; 10= Worst Pain Imaginable) for their back, and both legs (leg with worse pain and alternate leg). Mean score for both the back and symptomatic leg was 4 whereas the maximum alternate leg score was 1.
- **NASS Patient Satisfaction Evaluation (PSE):** Revealed 3 subjects had complete relief of symptoms and 3 had good relief indicating successful outcomes.
- **NASS:** Results listed in Table 3 suggest Satisfaction with procedure using Tripore.

Table 2: EQ5D-5L

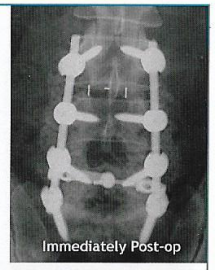
	Mobility	Self-Care	Usual Activities	Pain	Anxiety/ Depression
1 - No Problem	3	6	2	3	4
2 - Slight Problem	-	-	2	-	3
3 - Moderate Problem	4	1	2	2	0
4 - Severe Problem	-	-	1	2	-
5 - Extreme Problem	-	-	-	-	-

Table 3: NASS PSE

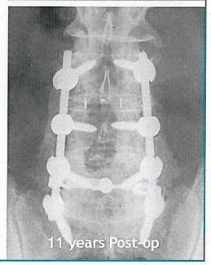
Pain Relief			Yes	No	Unsure
Complete	3	Would have the op again	5	1	1
Good deal	3	Would recommend to friends / family	7	0	0
Little	1	Were there areas for improvement in care	0	7	0
None	0				

X-Ray Results:

- Erect lumbar spine X-Rays were performed on all 7 subjects. For the 6 subjects that were not deemed clinical failures in the initial study, long term radiological follow up showed evidence of successful bone formation. There were no cases of instrumentation failure or screw loosening.
- Representative images from Case 5 show a stable fusion following substantial TriPore conversion from its granular form to mature bone with extensive remodeling over 11 years.


Immediately Post-op


12 months Post-op


11 years Post-op

Conclusions

- Previous clinical data evaluating TriPore HA at 12 months post surgery supported its use as an alternative to iliac crest autograft in lumbar spine fusions.
- Patient evaluations conducted 10+ years post surgery using TriPore HA demonstrate:
- - Radiologic evidence of graft consolidation and formation of bone, and
  - Long term satisfaction with the procedure and functioning
- Additional studies with larger sample sizes will be needed for a full assessment of efficacy, however this data supports the long term stability of TriPore 10+ years post implant.

References:

[1] D'Souza, W., Birch, N. Orthogem TriPore HA and Bone Marrow Aspirate used in lumbar spinal fusion: 12 month clinical and radiological review. (2008 - data on file: Orthogem Ltd, Biocity, Nottingham)

[2] Lo, W., Et al. Orthogem Tripore HA: a new resorbable hydroxyapartite bone graft substitute: Proof of biological concept in a long-term sheep femoral condyle model.

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Disclosure: Nick Birch is a consultant to and shareholder of Orthogem Ltd