SUMMARY

CLINICAL CASE REPORTS

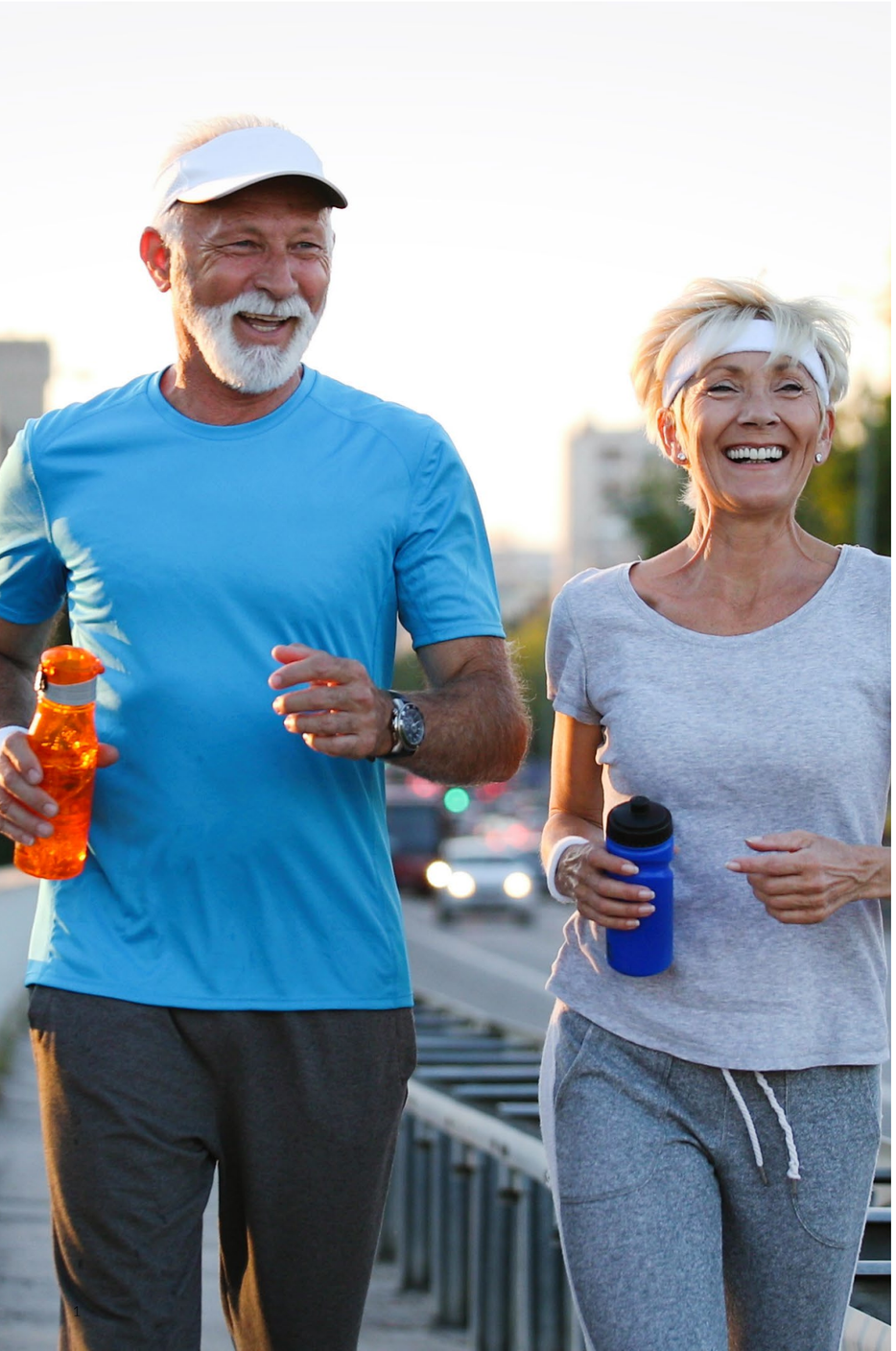
NOVABONE®

SUMMARY CLINICAL CASE REPORTS 2024

Table of

Contents

Intro



We're Developing a Breakthrough in Bone Grafting Materials

NovaBone, with over 20 years of experience in the field of orthobiologics, specializes in developing biomaterials that leverage the body's natural healing process while addressing the specific requirements of orthopedic surgeons.

Our products have garnered international recognition and trust, with over 2 million devices implanted worldwide and support from extensive clinical and scientific publications.

ORTHOPEDICS

Educational Disclaimer

The authors, editors, and publisher have taken great care to ensure that the drug, device, and material selections and applications provided in this publication align with prevailing recommendations and practices at the time of publication.

Nevertheless, in light of ongoing research, evolving government regulations, and the constant influx of information pertaining to surgical procedures, grafting materials, and techniques, we strongly encourage readers to consult the package insert before employing any discussed material. Be vigilant for any alterations in indications and additional warnings and precautions, especially when dealing with newly introduced or rarely utilized agents.

It is crucial for readers to recognize the potential risks associated with incorporating unfamiliar techniques and procedures into their practices. Treatment decisions ultimately rest with individual surgeons, who exercise their professional judgment in each unique situation. We recommend that readers seek professional advice from their colleagues and advisors.

The Company cannot guarantee the accuracy, comprehensiveness, or timeliness of the information presented and disclaims responsibility for any claims, injuries, damages, or losses stemming from the use of or reliance on the material presented or techniques demonstrated. Healthcare professionals or any other individuals may make such claims.

Posterior Spinal Fusion Using Bone Graft Substitutes

N.K. Anjarwalla*[1], P Robbins[2], J Hucker[1], S.P.F. Hughes[1]

Presented at the International Society for Lumbar Spina Annual Meeting, Adelaide, Australia, 2000. 1. Department of Orthopaedics, Charing Cross Hospital, ICSM, and 2. Academic Department of Imaging, Hammersmith Hospital.

Introduction:

Posterior and lateral mass fusion are recognized treatments for spinal instability. Bony fusion is often enhanced by autograft harvested from the iliac crest. This is associated with a significant morbidity[i] and has stimulated the development of bone graft substitutes, such as Bioglass 45S5 a melt derived glass, composed of sodium, calcium, silicon and phosphate. In vitro Bioglass® is known to stimulate osteoblast proliferation and the production of bone nodules[ii]. Animal studies have shown Bioglass® to be as efficacious as autograft[iii].

Hypothesis:

Bioglass® can be used as a bone graft adjunct reducing the need for autologous bone graft. It is a safe material and the success of fusion should not be affected.

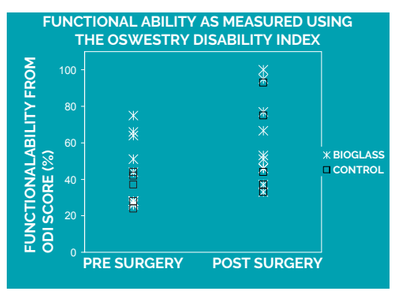
Aims:

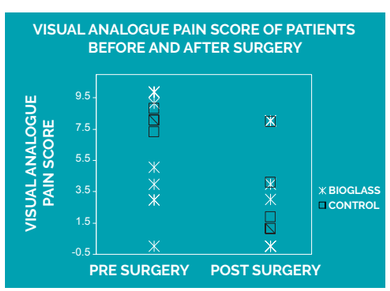
- To show Bioglass® may safely be used as a bone graft adjunct
- To show Bioglass® is a safe material to use in posterior spinal fusion

Method:

Patients were recruited from our pre-admission clinics. After obtaining written consent, patients were randomly allocated to two groups: Group 1 - fusion supplemented with autologous bone only Group 2 - autologous graft on one side of their spine and a 50/50 mixture of graft and Bioglass® on the other. Patients were assessed by an independent observer; function using the Oswestry Disability Index, pain using visual analogue scales, X-rays were performed on all patients and bone densitometry on some. This was repeated at 1, 3, 6 and 12 months post operatively.

Outcome was graded as excellent, good, fair or poor - determined by their return to work, regular activities, analgesic requirement and neurological deficit. Surgery was performed exclusively by two spinal surgeons in our unit. Randomization occurred in theatre. Post operatively patients were mobilized with the assistance of a physiotherapist and discharged when deemed safe. 15 patients have been followed up for greater than 6 months. Control group n= 5. All female. Average age 46 + 15years. In the study group which received autologous bone on one side and a mixture of autologous bone and Bioglass® n= 10. 5 were female and the average age was 50+ 24 years.



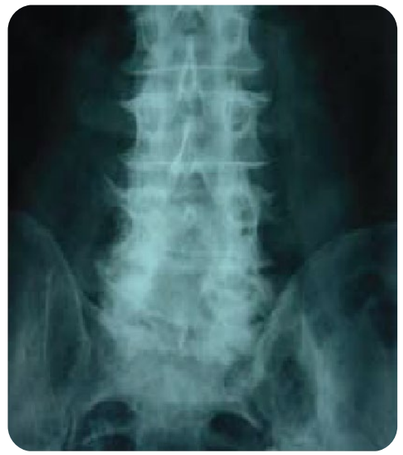


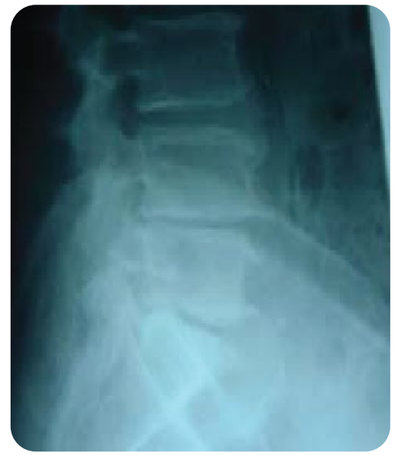
Plot of the change in functional ability of patients (100% being fully functional) in the plot above, and change in the level of pain, in the plot below, before and after surgery in the two groups. There was no significant difference between the two groups.

Results:

	BG	Control
Excellent	5(50%)	2(40%)
Good	1(10%)	1(20%)
Fair	1(20%)	1(20%)
Poor	2(20%)	1(20%)

Table of results showing the outcome of fusion in the control and study group -BG. A 60% excellent/good outcome is comparable with other authors[iv]. Within the Bioglass group there was a significant improvement in pain ($p < 0.05$ t test) and function ($p < 0.01$)





X-rays of a patient who received autograft on one side and a mixture of Bioglass® and autograft on the other demonstrating fusion at 6 months. There was no evidence of pseudarthrosis in any of the patients.

Summary:

The results of surgery from this study produced a 60% good or excellent result. We have shown that the preliminary results of spinal fusion using a mixture of autograft and Bioglass® is equally successful as autograft alone. There were no adverse reactions to the material.

Conclusion:

There is a need for a safe alternative to autologous bone graft. The use of allograft is associated with a risk of infection transmission[v]. Recombinant technology will soon make Bone Morphogenetic Proteins widely available for clinical use. These proteins, that are able to stimulate bone formation and fusion[vi], require a carrier. We propose that a combination of these proteins with a bioactive material such as Bioglass®, that is also able to act as a bone graft adjunct may well be a successful alternative to autologous bone graft.

References:

i. Summers B.N., Eisentstein S.M. Donor site pain from the ilium. A complication of lumbar spine fusion. Journal of Bone and Joint Surgery [Br] 71: 677-680 (1989)
ii. Price-N; Bendall-SP; Frondoza-C; Jinnah-RH; Hungerford-DS Human osteoblast-like cells (MG63) proliferate on a bioactive glass surface. J-Biomed-Mater-Res. 1997 Dec 5; 37(3): 394-400
iii. Oonishi H., Kushitani S., Yasukawa E., Hiroyoshi I., Hench L.L., Wilson J., Tsuji E., Sugihara T. Particulate Bioglass Compared with Hydroxyapatite as a Bone Graft Substitute. Clinical Orthopaedics and Related Research 334:316-325 (1997)
iv. Nork S.E., Hu S.S., Workman K.L., Glazer P.A. Bradford D.S. Patient outcome after spinal decompression and Instrumented posterior spinal fusion for degenerative spondylolithesis. Spine 24 (6) 561-569 (1999)
v. Buck B.E., Malinin T.i., Brown M.D. Bone transplant and human immuonodeficiency virus. Clinical Orthopaedics and Related Research. 240:129-136 (1989)
vi. Cook S. D., Dalton J.E., Tan E.H., Whitecloud T.S., Rueger D.C. In vivo evaluation of recombinant human osteogenic protein (rhOP-1) as a bone graft substitute for spinal fusions. Spine 19(15) 1655-1663 (1994)

The Clinical Evaluation of NovaBone for the Treatment of Tibial Fractures

Hao Sichun, MD – Orthopedic Department, The First Affiliated Hospital of Suzouh University Jiangsu Med.,
Feb 2004, Vol 30, No.2, p84-87

Introduction:

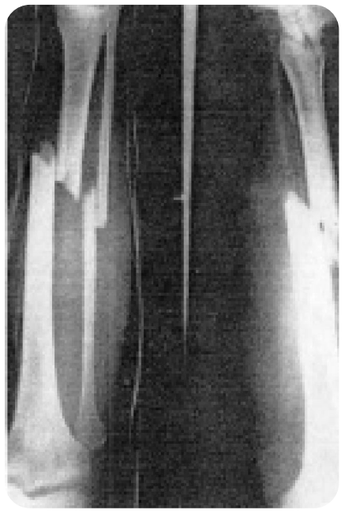
Tibial fractures are known to have long healing times and high rates of bone nonunion. Therefore the authors set out to expedite the healing rate of bone fractures and lower the rate of bone nonunion. In this study the author selected to use NovaBone Particulate to accelerate the healing process and repair damaged bone.

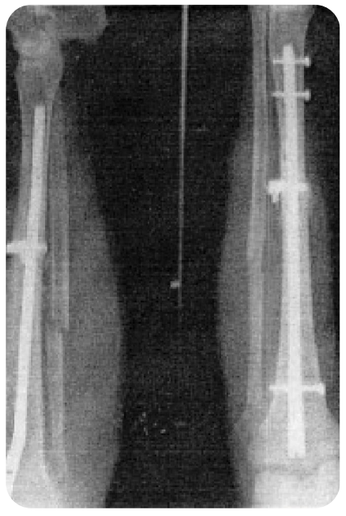
Method:

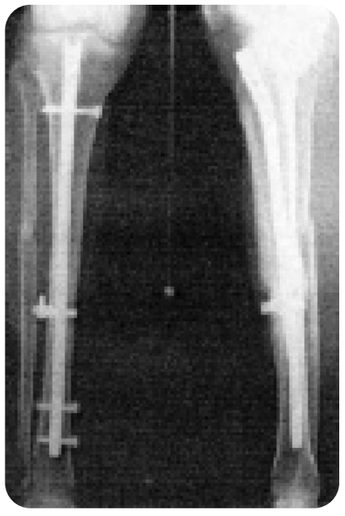
NovaBone was used in the experimental group in conjunction with open reduction and internal fixation of tibial fractures from March 2002-January 2003. A total of 78 patients were treated for fresh fracture of the tibia injuries, 47 Male Cases, 31 Female Cases, Ages 17-78 years old, Average Age 40.5 years old. Patients were randomly divided into 40 cases for the experimental group (fractured part of the bone was treated with NovaBone) and 38 cases for the control group (did not receive NovaBone).

Surgical Indications:

One third of the middle, top, and bottom borders of closed fractures or I°-II° open fractures used interlocking nail fixation, while fractures near the knee or ankle used steel plate fixation.







Results:

All patients received between 5-8 months of follow up visits, averaging 6 months. The experimental group's clinical and bone healing time was 9-10 weeks and 11-12 weeks respectively. Clinical and bone healing times of the control group were 13.5-14.5 weeks and 15.5-16.5 weeks respectively. The healing time of the control group were all later than the experimental group by 4-5 weeks.

Table of Results:

Exp. Group	Week 8	Week 12	Week 16
40 Cases	12 Excellent 28 Good	35 Excellent 5 Good	40 Excellent
Control Group			
38 Cases	6 Good 20 Okay 12 Poor	2 Excellent 25 Okay 10 Poor 1 Poor	37 Excellent 1 Okay

Discussion:

Tibial fractures are very common and with surgical procedures including nails, pressurization, or steel plate internal fixation, etc. However common disadvantages of all of the above methods are that they take a long time for fractures to heal. Reports in the literature show non-union rates as high as 20%-40%. This experimental group was treated with NovaBone on the fracture line or defect site after internal fixation. As a result, clinical and bone healing times were all 4-5 weeks shorter than the control group. NovaBone showed a clinical ability to expedite bone healing and should routinely be used in the clinical setting.

Anterior Lumbar Interbody Fusion - NovaBone in Conjunction With Femoral Ring Allograft

CLINICAL STUDY WITH 20 PATIENTS PRESENTED AT THE SECOND INTERNATIONAL CONGRESS OF CHINESE ORTHOPEDIC ASSOCIATION, 2007

Seth Zeidman, MD, Rochester Brain & Spine, Rochester, NY

Introduction:

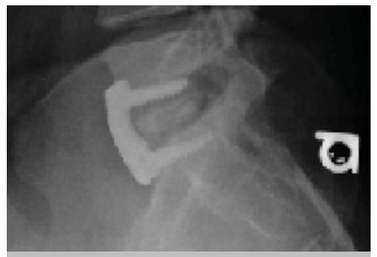
NovaBone Bioactive Synthetic Bone Graft has proven to control human osteoblasts cell cycle to favor proliferation and differentiation of only the cells that can proceed toward creation of a mineralized ECM, osteocytes, and new bone[1].
Clinical studies have also shown the material to be as efficacious as autograft in[2]. The intention of this investigation is to show the clinical experience of NovaBone as a bone graft substitute capable of inducing new bone formation.

Method:

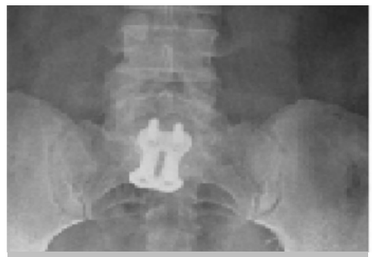
A retrospective chart and radiographic review was conducted on twenty patients who underwent a one or two level anterior lumbar interbody fusion in which a femoral ring allograft, packed with NovaBone, with an anterior tension band plate were used.

Results:

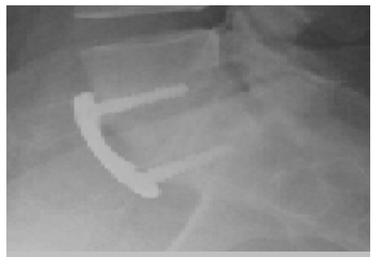
Twenty patients, aged 20 to 65 underwent an anterior lumbar interbody fusion with a one year follow up. Plain radiographs were reviewed at multiple time points with fusion assessed in 100% of patients (20 out of 20).



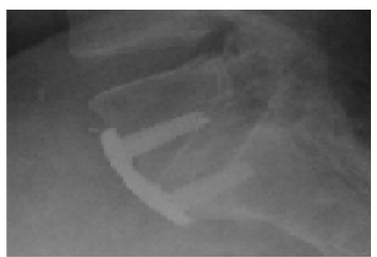
4 Months Postoperative



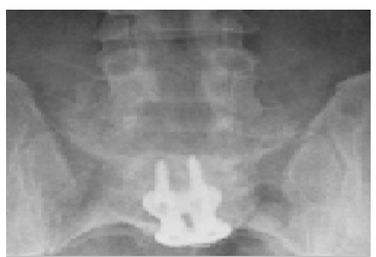
6 Months Postoperative



6 Months Postoperative



8 Months Postoperative



8 Months Postoperative

Discussion:

Evolution in the field of osteobiologics has enabled surgeons to avoid complications or morbidities associated with bone graft harvesting. In this investigation, NovaBone Putty was shown to be an easy to use, bone graft substitute capable of inducing new bone formation. Twenty (100%) of twenty patients were found to be fused on radiographical studies.
The advantage to packing NovaBone in the femoral ring allograft is to minimize the incidence of nonunion, while avoiding the possible complications or morbidities associated with bone graft harvesting.

Conclusion:

The use of NovaBone has shown in this study to be a viable alternative to achieve solid lumbar fusions, avoiding complications or morbidities related to bone graft harvesting such as pain and infection. It also proved to be a low cost alternative to commercially available bone morphogenetic protein. Follow up long term studies with large patient cohorts will be necessary to ascertain whether NovaBone is superior to autograft or commercially available bone morphogenetic proteins.

References:

1. Hench, L.L., Gaisser D.M., “The Genetic Basis for Osteogenesis Stimulation by Controlled Release of Ionic Dissolution Products.” Presentation #1697, in Transactions, 54th Annual Meeting of the Orthopedic Research Society. San Francisco, March 2-5, 2008.
2. Ilharreborde, B., et al., “Bioactive Glass as a Bone Substitute for Spinal Fusion in Adolescent Ioiopathic Scoliosis –A Comparative Study with Iliac Crest Autograft.” J Pediatr Orthop. Volume 28, Number 3, April/May 2008.

Anterior Cervical Discectomy and Fusion Utilizing a Novel Bioactive Glass Compound Increases Fusion Rate while Minimizing Complication

CLINICAL STUDY WITH 64 PATIENTS PRESENTED AT SECOND INTERNATIONAL CONGRESS OF CHINESE ORTHOPEDIC ASSOCIATION, 2008

Seth M. Zeidman, MD Rochester Brain & Spine, Rochester, NY

Introduction:

While Iliac crest autograft remains the gold standard material for spinal fusion, its use is limited by additional operative time, increase blood loss, and morbidity. The incidence of pseudoarthrosis after multisegmental anterior cervical fusion is directly proportional to the number of levels of arthrodesis. Osteobiological adjuvants offer an opportunity to reduce both the probability of pseudoarthrosis and the necessity for posterior instrumentation. However, the use of BMPs as an adjunct to cervical fusion has been associated with a dramatic number of peri-operative complications.

Recently, a synthetic osteoconductive bone graft composed of bioactive glass (NovaBone, Gainesville, FL) has shown significant efficacy. While concentrations of bioactive glasses have exhibited osteogenic potential, recent studies have demonstrated low concentrations of bioactive glasses are distinctly angiogenic. The pro-angiogenic capacity of this material is related to the soluble dissolution products of bioglass and the subsequent production of cell-secreted angiogenic factors by stimulated cells.

Methods:

We present our results using bioactive glass as an adjunct to structural arthrodesis to facilitate bone healing and do so in a controlled fashion. 64 patients underwent anterior cervical discectomy and fusion utilizing allograft bone supplemented by bioactive glass. One, two and three level fusions were performed. All patients had placement of an anterior cervical spine locking plate.

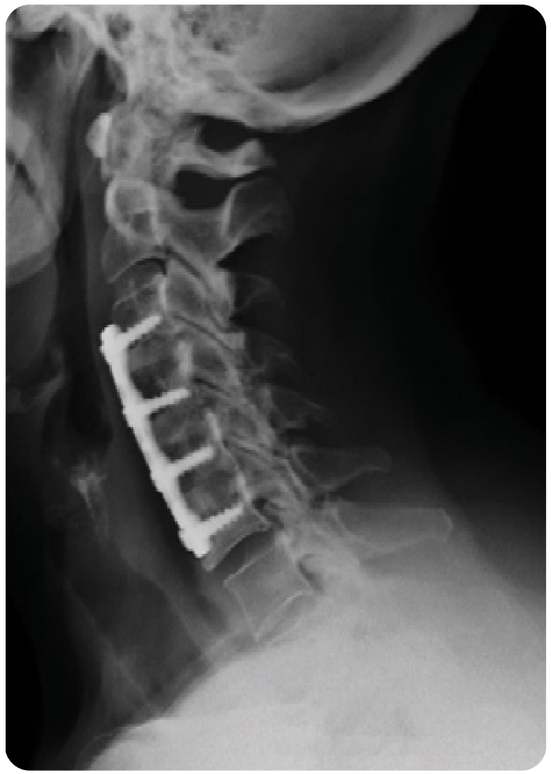
Results:

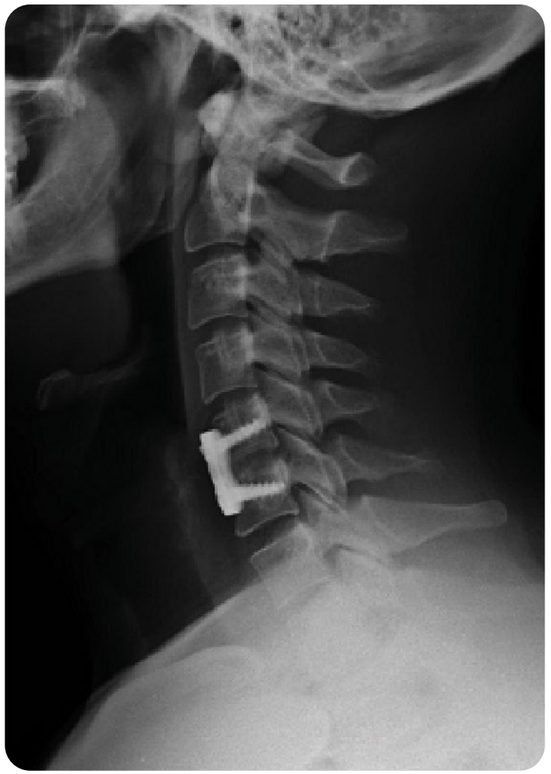
Overall incidence of fusion was 97% utilizing the combination of allograft bone with bioactive glass supplementation.
Use of the bioactive glass compound resulted in more rapid solid bony fusion. None of the patients sustained any complications associated with the surgery, the bone graft and/or the bioactive glass.

Complications:

Swallowing difficulty	0/64
Hoarseness/Dysphonia	0/64
Return to OR	0/64
Bleeding	0/64
Infection	0/64

The low incidence of non-union or pseudoarthrosis was much better than historical controls without the bioactive glass.





Conclusion:

Supplementation of standard allograft fusion with a bioactive glass compound facilitates more rapid and complete stable bony arthrodesis. This is achieved without the side effects of alternative biomaterials. Use of bioactive glass is safe and effective at a much lower overall cost.

The Use of a Calcium Phosphosilicate in Lower Lumbar Spinal Fusion

AN ANALYSIS OF NOVABONE IN LOWER LUMBAR POSTEROLATERAL SPINAL FUSION

Derek J. Thomas, MD; Harry J. Griffiths, MD; and James C. Perin, MD.

Thomas DJ, Griffiths HJ, Perrin JC. "The Use of a Calcium Phosphosilicate in Lower Lumbar Spinal Fusions". Clinical report from the Department of Orthopedic Surgery, Sewickly Hospital at Pittsburgh, PA (report available from NovaBone® Products, Jacksonville, FL). 2010

Investigation performed at the Department of Orthopaedic Surgery, Sewickley Hospital at Pittsburgh, PA

Abstract:

Over 12 months in a busy orthopaedic private practice, 22 patients received posterolateral spinal fusion in their lower lumbar spine. NovaBone, a calcium phosphosilicate bone graft substitute, was used in all 22 of these patients. The patients received the NovaBone bone graft with local bone or local bone and iliac crest bone graft (ICBG) as a composite. The results were largely excellent with only one patient experiencing non-union at two levels.

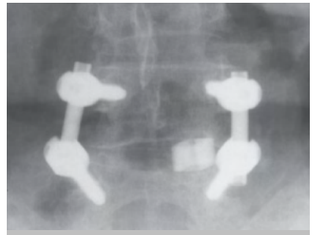
Methods:

There were 14 female patients and 8 male patients, ages ranging 31 to 84 (mean 59.0 years). All suffered from low back pain, leg pain or both. The location of the fusion was L4-5 in 14 patients, L4-S1 in 3 patients, L3-5 in 4 patients and L5-S1 in 1 patient. NovaBone and local bone graft were used in all 22 patients and iliac crest bone graft in 15 patients. All of the patients received a posterolateral spine fusion with NovaBone and local bone or NovaBone, local bone, and iliac crest bone. 9 patients also received an interbody fusion with a combination of the materials. Rods and pedicle screws were used in every case. All patients were evaluated and a posterolateral fusion (PLF) technique was conducted.

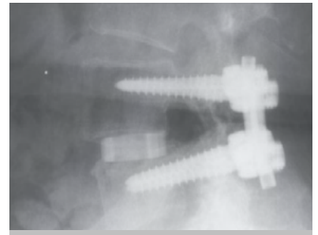
9 patients had the additional technique of interbody arthrodesis along with PLF. All patients received decompression for indications of degenerative disc disease, spondylolisthesis, spinal stenosis or other degenerative processes with fixation and instrumentation as required. Calcium phosphosilicate (10cc) was mixed with local bone in all patients. Iliac crest bone graft was mixed with local bone and calcium phosphosilicate (10cc) in 15 patients. The mixture was distributed into the posterolateral gutters and interbody space when a cage was used.

Results:

Of the 29 levels fused, there were only 2 instances of non-union. The first patient had a complete non-union initially treated with a bone growth stimulator, but required a second fusion. The other patient was fused at 2 levels; the upper level (L3/4) fused satisfactorily but the lower level (L4/5) failed to fuse, resulting in asymptomatic non-union. A third patient continued to have low back pain and despite radiographs appearing normal with a stable fusion, she underwent an open inspection of the fusion which appeared to be stable. All but one of the patients assessed themselves as very satisfied with the operative results stating a reduction in pain and symptoms and a return to a normal lifestyle.

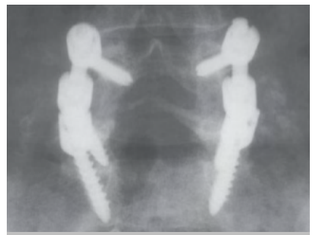


6 months AP Radiograph

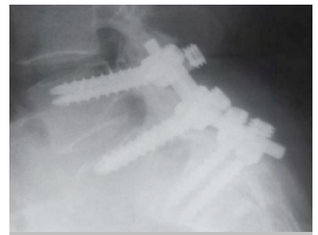


6 months Lateral Radiograph

Case Study I: EJ is a 73 year old female with an acute history of bilateral lower extremity pain and weakness. Pre-operative evaluation confirmed stenosis of L4-L5 with spondylolisthesis. Based upon the progression of symptoms, surgery was recommended. In February of 2009, the patient underwent a posterolateral fusion of L4-L5 with an anterior disc spacer. NovaBone (10cc) was combined with ICBG/local bone and 10cc was applied. Imaging at six months revealed solid bilateral fusion with remodeling (Fig. 1). Clinically, the patient's symptoms have resolved with improving lower extremity function.

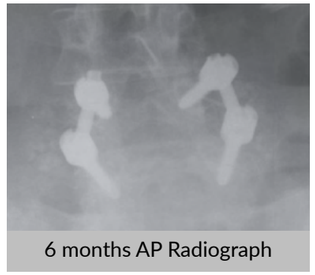


6 months AP Radiograph

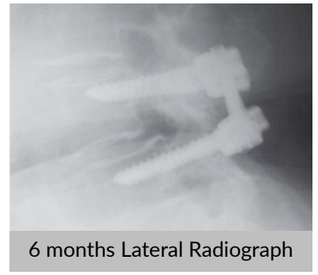


6 months Lateral Radiograph

Case Study II: MD is a 53 year old female with an acute history of LBP and bilateral lower extremity pain and weakness. Pre-operative evaluation confirmed stenosis of L4-S1 with spondylolisthesis. Patient was treated conservatively, without improvement. In February of 2009, the patient underwent a posterior L4-S1 laminectomy with posterolateral fusion. NovaBone (10cc) was combined with ICBG/local bone and applied as a graft composite. Imaging at six months revealed significant bilateral fusion with remodeling (Fig. 2). Clinically, the patient is doing well with resolution of her symptoms.

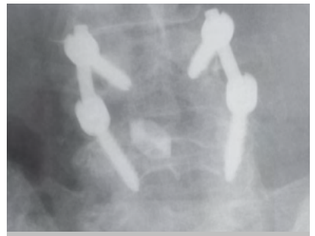


6 months AP Radiograph

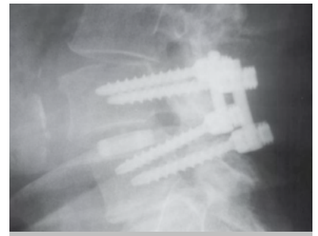


6 months Lateral Radiograph

Case Study III: NB is a 72 year old female with a chronic history of LBP and bilateral lower extremity pain and weakness. Pre-operative evaluation confirmed stenosis of L4-L5 with spondylolisthesis. The patient failed conservative management with steroid injections and pain medication. In December of 2008, the patient underwent a posterior fusion of L4-L5. NovaBone (10cc) was combined with local bone and 10cc was applied. Imaging at six months revealed bilateral fusion with remodeling (Fig. 3). The patient continues to do well at follow-up with minimal LBP and marked improvement in lower extremity pain and weakness.



6 months AP Radiograph



6 months Lateral Radiograph

Case Study IV: NSI is a 60 year old male with an acute history of LBP and bilateral lower extremity pain and weakness. Radiographic evaluation confirmed stenosis of L4-L5 with spondylolisthesis. The patient was treated using pain medication and steroid injections with no relief. In April of 2009, the patient underwent a transformational interbody fusion of L4-L5 with posterior fusion. NovaBone (10cc) was combined with ICBG/local bone and 10cc was applied. Follow-up imaging at six months revealed bilateral fusion and remodeling (Fig. 4). The patient continues to do well with minimal LBP and resolution of lower extremity pain.

Conclusion:

The retrospective study of 22 patients demonstrated NovaBone is an excellent bone graft extender. 15 out of 15 patients who had a single level fusion were successfully fused at 12 months, a 100% fusion rate. When adding the small cohort of patients who had a 2 level fusion to the data it is demonstrated that the fusion rate is 26 of 29 total levels fused, a fusion rate of 90%. 7 patients who had local bone with NovaBone had an 88.9% fusion rating after 12 months which compares favorably to the gold standard of ICBG (fusion rating of 89.7% after 32.5 months). The fusion rate of NovaBone calculated from the data demonstrates how NovaBone has a higher fusion rate than using ICBG alone or autograft with DBM. With an increase in the fusion rate there is an increase in the positive outcome for these patients.

Bioactive Glass as a Bone Substitute for Spinal Fusion in Adolescent Idiopathic Scoliosis

A COMPARATIVE STUDY WITH ILIAC CREST AUTOGRAFT

Brice Ilharreborde, MD; Etienne Morel, MD; Franck Fitoussi, MD; Ana Presedo, MD; Phillipe Souchet, MD; Georges-Francois Pennecot, MD; and Keyvan Mazda, MD.

Journal of Pediatric Orthopaedics, 2008 28(3):347-351.

Background:

While Iliac crest autograft remains the gold standard for spinal fusion, it is limited by operative time, blood loss, and morbidity. Recently, a synthetic osteoconductive bone graft material composed of bioactive glass has been described, with high effectiveness in animal models. Its ability to achieve spinal fusion in humans has never been reported. The aim of this study was to compare bioactive glass and iliac crest autograft as bone substitutes in the treatment of thoracic adolescent idiopathic scoliosis (AIS).

Methods:

Eighty-eight consecutive patients underwent posterior spinal fusion for progressive thoracic AIS. There were 2 study groups based on the type of bone graft used: iliac crest autograft (n=40) or bioglass (n=48). A minimum 2 – years follow-up was required. Medical data and radiographs were retrospectively analyzed and compared using unpaired t test and Mann-Whitney U test.

Results:

Mean follow-up was 40 months in the autograft group and 38 in the bioglass group. In the autograph group, there were 2 infections (5%) and 3 mechanical failures (7.5%). One infection (2%) and 1 early mechanical failure (2%) occurred in the bioglass group.

Loss of correction of the main thoracic curve between immediate postoperative and latest follow-up averaged 15.5% for the autograft group and 11% for the bioglass group (P = 0.025). The mean (±SD) gain of frontal balance between immediate postoperative latest follow-up was 0.8 (±9.3) mm in the autograft group and 8.1 (±12) mm for the bioglass group (P=0.005).

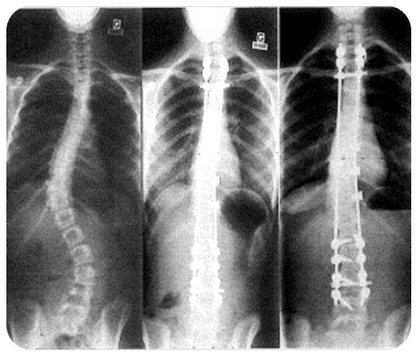


Figure 1. Preoperative, immediate postoperative, and latest frontal radiographs of a 15-years old patient who was operated using bioglass. Solid fusion was obtained at 32 months postoperative.

Conclusion:

Results of this retrospective study suggest that bioglass is as effective as iliac crest graft to achieve fusion and maintain correction in AIS. Less complications were seen in the bioactive glass group, but the difference did not reach statistical significance. Bioactive glass can be proposed in the treatment of AIS, avoiding the morbidity of iliac crest harvesting. However, clinical and radiographical outcomes need to be confirmed at long-term follow-up.

Key Words:

- Spine
- Adolescent
- Idiopathic scoliosis
- Bone substitute
- Bioglass.

TABLE 1. Demographics of Autograft Versus Bioactive Glass Group

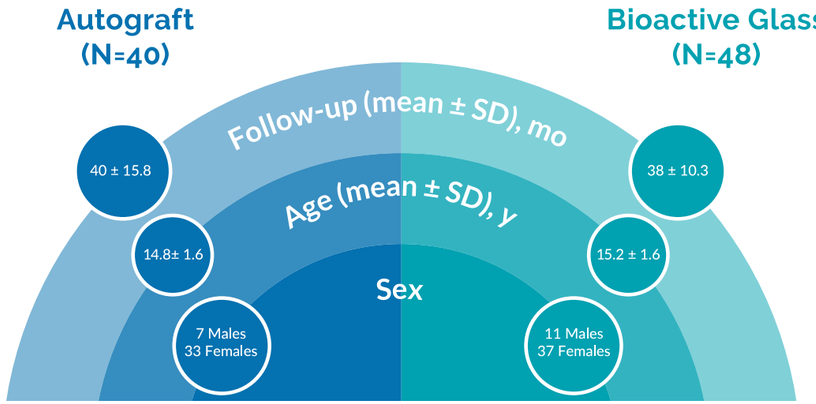


TABLE 2. Preoperative Radiographic Parameters of the 2 Study Group

	Autograft (N=40)	Bioactive Glass (N=48)
Main Thoracic Cobb Angle (mean ± SD), Degrees	55.7 ± 14.4	56.5 ± 19.8
Main Thoracic Curve Reducibility (mean ±SD), %	45.4 ± 16.8	50.7 ± 14.5
Frontal Imbalance (mean ± SD), Mm	13.6 ± 9.0	14.8 ± 10.9
T9 Sagital of fset (mean ± SD), Degress	-6.4 ± 5.4	-6.1 ± 5.8

TABLE 3. Radiographic Parameters of the 2 Study Group at Latest Follow-Up

	Autograft (N=40)	Bioactive Glass (N=48)
Main Thoracic Cobb Angle (mean ± SD), Degrees	31.1 ± 12.5	25.2 ± 12
Correction (mean ± SD), %	44.6 ± 16	55.3 ± 12.7
Frontal Imbalance (mean ± Sd), Mm	13.7 ± 8.5	13.0 ± 8.3
T9 Sagital of fset (mean ± SD), Degress	-5.8 ± 3.3	-6.9 ± 4

Open Curettage with Bone Augmentation for Symptomatic Tumors & Tumor-like Lesions of Calcaneus:

A COMPARISON OF BIOACTIVE GLASS VERSUS ALLOGENEIC BONE

Hongdong Ma, MD[1] , Yingxu Shi, MS[1] , Weilin Zhang, MD[2] , Fei Liu, MD[2] , Yaxin Han, MD[3] , Maowei Yang, MD[4]

[1]Resident Doctor, Department of Orthopaedics, the First Hospital of China Medical University, Shenyang, Liaoning, China [2]Doctor-in-Charge, Department of Orthopaedics, the First Hospital of China Medical University, Shenyang, Liaoning, China [3]Associate Senior Doctor, Department of Orthopaedics, the First Hospital of China Medical University, Shenyang, Liaoning, China [4]Chief Physician, Department of Orthopaedics, the First Hospital of China Medical University, Shenyang, Liaoning, China

The Journal of Foot & Ankle Surgery, 2021; 60 (2021): 881–886.

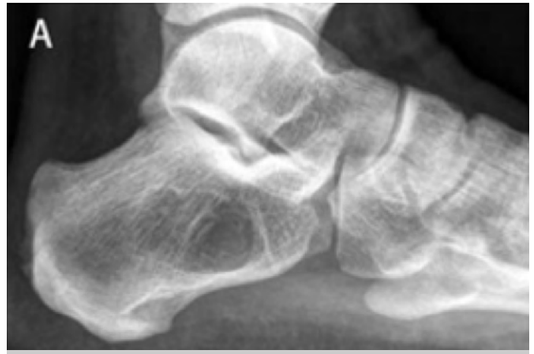
Abstract:

Few studies have characterized the clinical outcomes of 45S5 Bioglass applied as a bone graft to that of allogeneic bone applied in calcaneal open curettage. Therefore, the purpose of the present investigation was to compare the outcomes of patients with calcaneal tumors and tumor-like lesions treated by open curettage with 45S5 Bioglass or allogeneic bone. Of the 31 patients who underwent open curettage (18 cases of unicameral bone cysts, 7 cases of aneurysmal bone cysts, and 6 cases of intra-osseous lipoma), 16 (52%) received grafts with 45S5 Bioglass and 15 (48%) with allogeneic bone. All the feet achieved bone fusion according to the modified Neer radiographic classification system at the last follow-up examination. The mean bone in-growth time for the grafts with 45S5 Bioglass versus allogeneic bone was 3.71 ± 0.86 versus 4.46 ± 1.04 months (p = .038), the mean bone healing time was 4.86 ± 0.93 versus 5.73 ± 1.07 months (p = .021), and the mean incision drying time was 7.2 ± 1.8 versus 8.2 ± 1.5 days (p = .047), respectively. No differences were found in the postoperative American Orthopaedic Foot and Ankle Society ankle-hindfoot scale scores between the 2 groups (p = .213). These results show that 45S5 Bioglass can better facilitate the formation of new bone with a faster drying time of the incision than allogeneic bone. Although both materials can benefit the clinical outcomes of calcaneal tumors and tumor-like lesions, further studies are needed to observe the long-term complications and lesion recurrence rates.

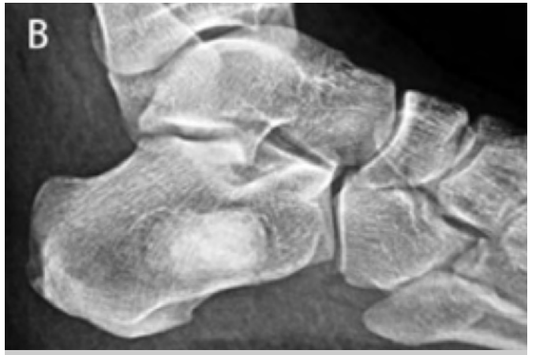
Discussion:

In conclusion, 45S5 Bioglass (NovaBone) and allogeneic bone can both be used as viable alternatives to autologous bone for calcaneal reconstruction after curettage of calcaneal tumors and tumor-like lesions. However, 45S5 Bioglass can shorten the bone ingrowth time, bone healing time, and incision drying time compared with allogeneic bone, and 45S5 Bioglass showed good tolerance to early weight-bearing, although it might be inferior to the allogeneic bone.

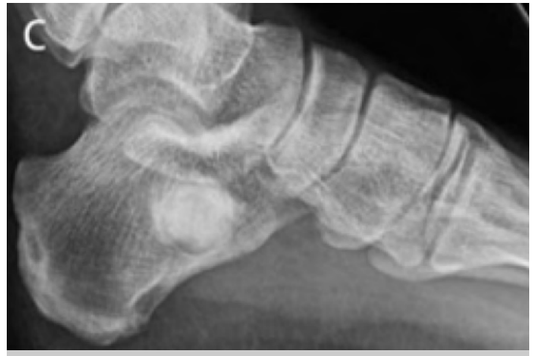
Compared with allogeneic bone, we recommend 45S5 Bioglass as a bone-filling material for reconstruction of central calcaneal defects after resection of tumors and tumor-like lesions.



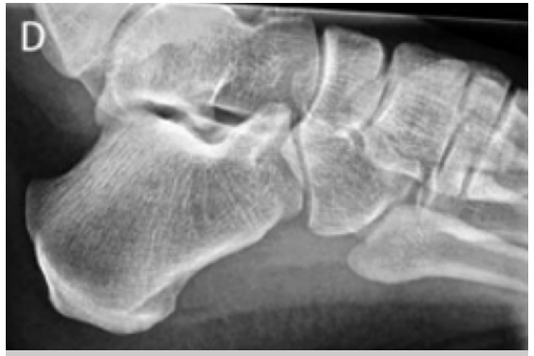
Before Surgery



5 Days Postoperatively



Bone Ingrowth At 12 Weeks Postoperatively



Bone Fusion At 17 Weeks Postoperatively

Lateral or oblique radiographs of the left calcaneus of a 36-year-old male with histological confirmed intraosseous lipoma. Bioglass 45S5 was used to reconstruct central calcaneal defects after curettage of the lesion.

Comparison of bone ingrowth time and bone healing time between groups (months) (n=31 feet of 31 patients)

	45S5 Group	Allograft Group	*p* Value
Bone Ingrowth Time	3.71 ± 0.86	4.46 ± 1.04	0.38*

Data presented as mean ± standard deviation. Abbreviations: 45S5, 45S5 Bioglass® (Novabone): Allograft, allogenic bone.
* The bone ingrowth time and bone healing time was significantly shorter in the 45S5 group than in the allograft group (*p*<.05)

Clinical Case Report: “Use of Novabone in an L2-3 and L3-4 Posterior Lumbar Interbody Fusion Case.”

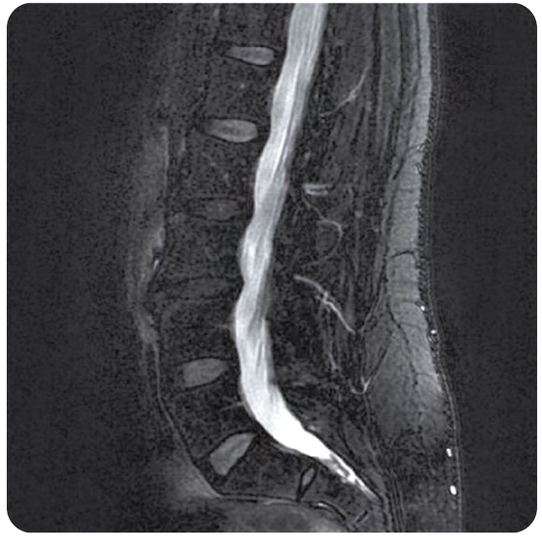
COURTESY OF DR. JOHN C. STEVENSON - THE SPINE AND NEUROSURGERY CENTER, GAINESVILLE, FLORIDA

50-years old white female with a history of lower back pain dating back to her mid-teens. She felt that her pain began after participating in school sports. Her back pain was moderate in nature, with pain that would radiate down to her right leg to her foot, including mild right leg weakness. Her back and leg pain were equal in terms of severity. She had constant back pain which was aggravated by sitting and activity but was somewhat relieved by rest, ice, and heat.

Her symptoms failed to improve with conservative treatment which consisted of oral anti-inflammatories, muscle relaxants, chiropractic manipulation, and physical therapy. She smoked one and a half packs of cigarettes per day. Her neurological exam was normal except for the lumbar paraspinous muscle spasm.

Pre-Operative Sagittal MRI-Scan

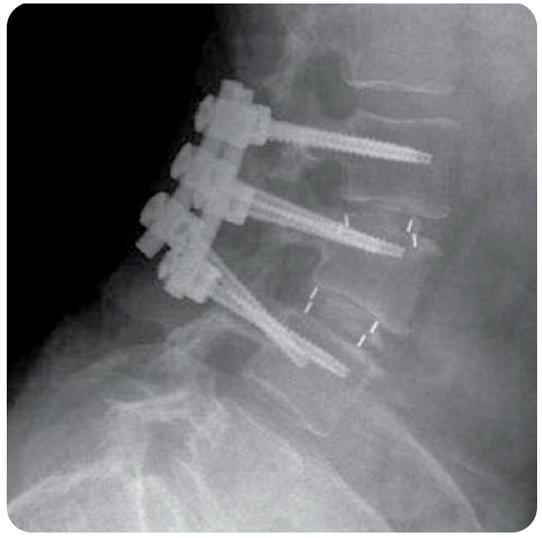
Radiographic Studies:



Pre-operative MRI demonstrated degenerative disc disease at L2-3 and L3-4 with mid-disc space collapse at L3-4.
There was also evidence of right L3-4 foraminal narrowing.

Post-Operative Flexion Extension Lumbar X-Ray, three-months

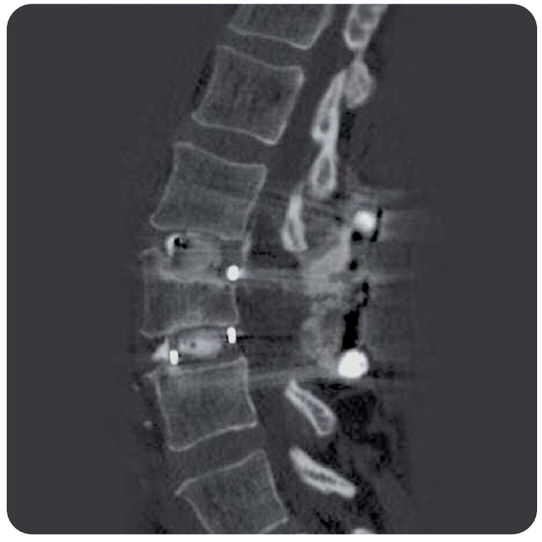
Operative Technique:



The procedure performed was a L2-3 and L3-4 posterior lumbar interbody fusion with Peek cages and pedicle screws. The cages were packed with NovaBone. NovaBone was also placed in the disc space between and ventral to the cages. The facet joints were decorticated.

Post-Operative Sagittal CT Scan, three-months

Outcome:



The patient had good reduction of back and leg pain at the three-months follow-up appointment. The three-months flexion extension lumbar plain X-ray demonstrated no motion and evidence of bone in the disc interspace. A three-month CT Scan demonstrated bone in the disc interspace within and between cages.

Clinical Case Report: “Novabone in the Cervical Spine (Clinical Follow-Up of 10 Cases – Anterior Cervical Discectomy and Fusion).”

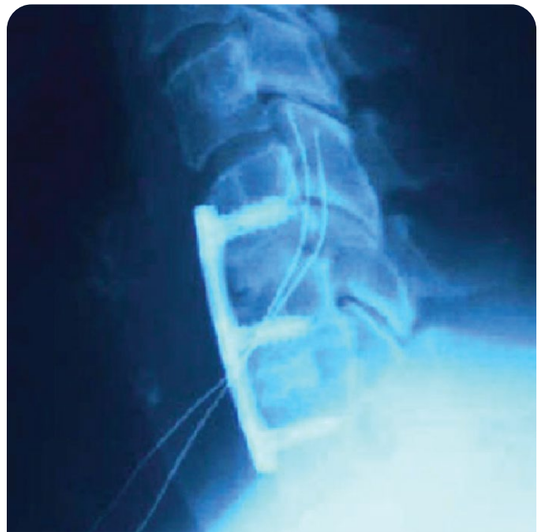
COURTESY OF DR. W.S. (BILL) EDWARDS - THE SPINE AND NEUROSURGERY CENTER, GAINESVILLE, FLORIDA

Introduction:

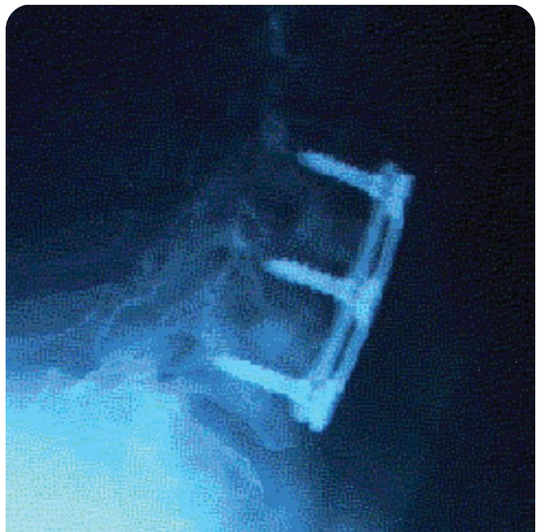
The following is a clinical review of ten consecutive patients with NovaBone utilized to augment bone healing with cervical allograft. These cases represent typical cervical disc herniation or cervical spondylosis patients with mechanical neck pain and radicular shoulder and arm pain that have had one, two and in one case three fusion surgery performed at the same surgical sitting. There are a minimum 16 weeks of follow up for each of these patients.

Materials:

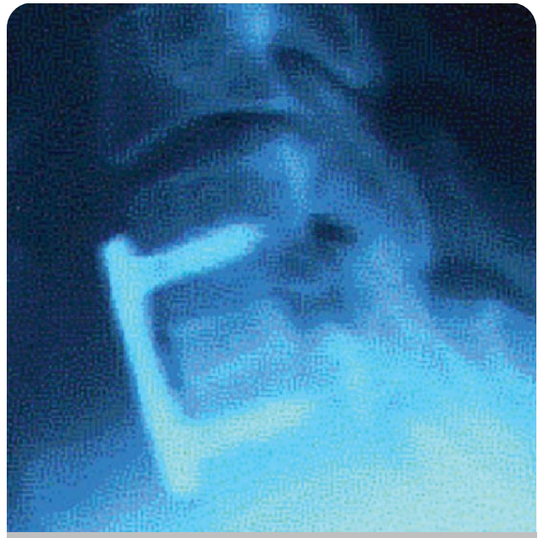
In each of the patients, an allograft threaded dowel was used. Autogenous bone harvested from the surrounding surgical was mixed with NovaBone and placed in the center of the dowel. NovaBone was also placed in surrounding areas around the dowel.



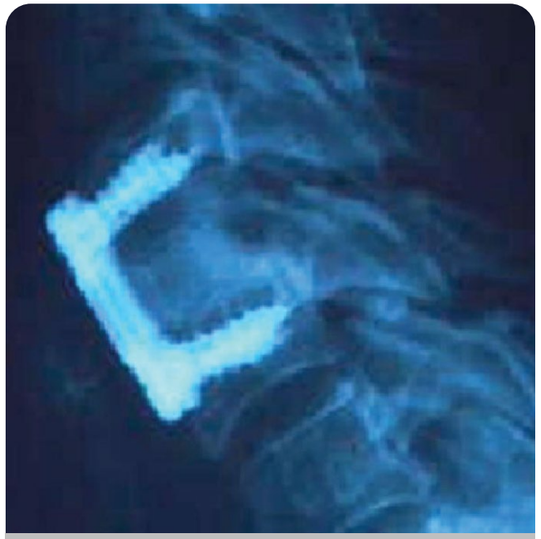
Patient No.2, 12 week X-ray



Patient No.3, 12 week X-ray



Patient No.6, 12 week X-ray



Patient No.7, 12 week X-ray

	Spinal Segment	Results
Patient #1	ACD/F C6-7	Completely healed in about 12 weeks
Patient #2	ACD/F C5-6 & C6-7	Solid arthrodesis at 12 weeks
Patient #3	ACD/F C4-5 and C5-6	Healing both levels in 12 weeks
Patient #4	ACD/F C4-5 above remote fusion from C5-5 and C6-7	Solid healing at 12 weeks
Patient #5	ACD/F C3-4	Apparent solid healing at six weeks; lost to follow up from there
Patient #6	ACD/F C6-7	Solid healing 12 weeks follow up
Patient #7	ACD/F C4-5	Solid fusion in 16 weeks
Patient #8	ACD/F C4-5	Healing at 12 weeks
Patient #9	ACD/F C3 to C6	12 week follow up solid union at c6-7
Patient #10	ACD/F C4 to C7	Sixteen week follow up showed solid healing of all three levels

Conclusion:

- The use of NovaBone continues to be a valuable adjunct in bone healing
- There were no problems related to soft tissue irritation or inflammatory reaction from NovaBone
- There is no evidence of pseudoarthrosis in any of these cases
- All patients have done well

Building Strong Bone Fast

PRODUCT CATALOG

NovaBone products harness the power of nature and integrate it with state-of-the-art synthetic technology to create superior bone grafting solutions that accelerate the healing process and promote the growth of natural hard and soft tissues.

Ready to Use Bone Grafts:

NovaBone Putty®

Description	U.S. Product Number	International Product Number
0.5cc Novabone Putty CMF	N/A	770600
1.0cc Novabone Putty CMF	N/A	770601
Putty Clamshell 2.5cc	NB0602	770602
Putty Clamshell 5.0cc	NB0605	770605
Putty Clamshell 10cc	NB0610	770610
Putty Syringe 0.5cc	N/A	771600
Putty Syringe 1.0cc	NB2601	771601
Putty Syringe 2.5cc	NB2602	771602
Putty Syringe 3.0cc	N/A	771603
Putty Syringe 5.0cc	NB2605	771605
Putty Syringe 10cc	NB2610	771610
Putty Tapered Syringe 2.5cc	NB2702	N/A
Putty Tapered Syringe 5.0cc	NB2705	N/A

MIS System

Description	U.S. Product Number	International Product Number
MIS Cartridge Refill 5.0cc	NB6650	772605
MIS Cartridge System 10cc	NB6610	772610
MIS Putty System 15cc	NB6615	772615
MIS Cartridge System Handle	NB6600	772600

MacroPor Si+™

Description	U.S. Product Number	International Product Number
MacroPor Si+ 1.6cc	NB2501	772501
MacroPor Si+ 2.6cc	NB2502	772502
MacroPor Si+ 5.0cc	NB2505	772505
MacroPor Si+ 8.0cc	NB2508	772508
MacroPor Si+ 10cc	NB2510	772510
MacroPor Si+ 15cc	NB2515	772515

NovaBone IRM™

Description	U.S. Product Number	International Product Number
1.0cc	NP0601	770401
2.5cc	NP0602	770402
5.0cc	NP0605	770405
10cc	NP0610	770410
15cc	NP0615	770415
IRM MacroPor 1.6cc	NP2501	772501
IRM MacroPor 5.0cc	NP2505	770505
IRM MacroPor 10cc	NP2510	770510
IRM MacroPor 15cc	NP2515	770515

Hydratable Bone Grafts:

OS-Si+ Morsels™

Description	U.S. Product Number	International Product Number
5.0cc Morsels 1-2mm cup	NB1805	770905
5.0cc Morsels 2-5mm cup	N/A	770805
10cc Morsels 1-2mm Syringe	NB4810	771810
10cc Morsels 1-2mm cup	NB1810	770910
10cc Morsels 2-5mm Syringe	NB3810	772810
10cc Morsels 2-5mm cup	NB0810	770810
15cc Morsels 1-2mm Syringe	NB1815	772815
15cc Morsels 2-5mm cup	NB3815	770815

Bioactive Strip™

Description	U.S. Product Number	International Product Number
50mmx25mmx4mm	NB2305	772305
50mmx25mmx8mm	NB2310S	772310S
100mmx25mmx4mm	NB2310L	772310L
100mmx25mmx8mm	NB2320	772320

MacroFORM™

Description	U.S. Product Number	International Product Number
Moldable Composite 2.5cc	NB4302	774302
Moldable Composite 5.0cc	NB4305	774305
Moldable Composite 10cc	NB4310	774310

Clinical Success with Novabone Ortho Products

Share your case with us

NOVABONE®

novabone.com
info@novabone.com
855.265.8013
13510 NW US Highway 441
Alachua, FL 32615

Made from recycled paper.

Halma

NovaBone is a Halma, PLC Company

NovaBone is a Halma company. Halma is a global group of life-saving technology companies with a clear purpose to grow a safer, cleaner, healthier future for everyone, every day.