

NOVABONE® Foot & Ankle

Clinical Case Reports & Bench Studies

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Precontoured Wedge Dissolution & Mechanical Integrity

NovaBone Products LLC. – Data on File

Introduction:

NovaBone's bioactive precontoured wedges are designed for osteotomy procedures. Their dissolution profile and mechanical properties were tested to evaluate their performance under simulated physiological conditions. The objective of this study was to assess how bioactive precontoured wedges dissolve over time and how this affects their mechanical integrity.

Methods:

Product:

- NovaBone's Bioactive Precontoured Wedges
  - **Material:** Bioglass 45S5 with Interconnected Porosity
  - **Dimensions:** 8mm x 9.4mm x 25mm

Sample Groups:

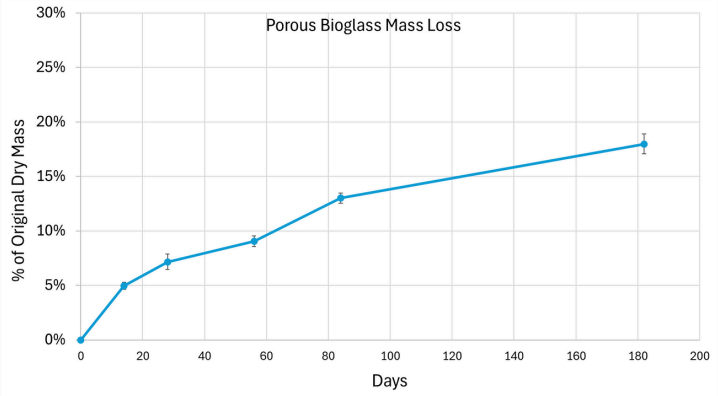
A quantity of N = 5 samples were tested at each six aging timepoints (0, 14, 28, 56, 84, and 182 days). Device aging was conducted in TRIS buffer at body temperature to simulate physiological conditions.

Testing:

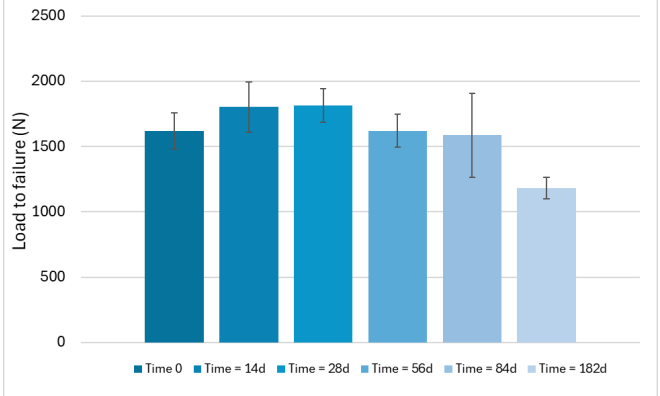
Two measurements obtained at each time point: mass (indicative of dissolution) and compression strength.

Results:

Dissolution Profile



Compression Strength



Key Findings:

Mass loss was approximately linear with time. The average mass loss was 17.98% after 182 days. Load to failure also decreased over time but remained over 1000 N through 182 days.

Precontoured Wedge Dynamic Loading

NovaBone Products LLC. – Data on File

Introduction:

NovaBone's bioactive precontoured wedges are designed for osteotomy procedures. Their mechanical properties were tested to evaluate their performance under biologically relevant loads. The objective of this study was to assess how well these wedges withstand dynamic mechanical stresses over time, ensuring surgical site stability and minimizing graft failure risks.



Methods:

Product:

- NovaBone's Bioactive Precontoured Wedges
  - **Material:** Bioglass 45S5 with Interconnected Porosity
  - **Dimensions:** 8mm x 9.4mm x 25mm

Sample Groups:

A quantity of N = 5 samples were tested at each three aging timepoints (0 weeks, 4 weeks, & 8 weeks). Device aging was conducted in TRIS buffer at body temperature to simulate physiological conditions.

Loads:

All samples were tested with a maximum compression load of 392.4 N and a minimum load of 39.24 N, simulating realistic physiological stress. Devices were tested in cyclic series of up to 1000 cycles.

Results:

Test Results Summary:

Device Group	0 weeks	4 weeks	8 weeks
Precontoured wedge	1000 ± 0 cycles	1000 ± 0 cycles	1000 ± 0 cycles

Note: Data is in number of cycles completed on average (out of 1000) ± 1 standard deviation. The maximum testing force per cycle was 392.4 N for all tests.

Key Findings:

The bioactive precontoured wedges showed consistent mechanical integrity, withstanding 1000 loading cycles across all time points (0, 4, and 8 weeks).

Osteostimulation of Bioglass

NovaBone Products LLC. – Data on File: see www.novabone.com/references

Why Bioglass?

Bioglass 45S5 is a pioneering biomaterial composed of: SiO_2, CaO, Na_2O, and P_2O_5. Its osteostimulative and osteoconductive properties make it an ideal material for bone tissue regeneration.

Bioglass key benefits include:

- **Grows strong bone faster** than simple osteoconductive synthetics (demonstrated with in vivo tests)
- **Stimulates osteoprogenitor cells** via continuous ionic release
- **Fully resorbs in 8 - 12 months***, allowing new bone formation throughout a defect
- **Facilitates rapid vascularization** and cellular response across interconnected amorphous structure
- **Enhances bone cell adhesion** by mimicking bone composition via formation of hydroxyapatite layers on the surface
- **Supports patient safety** by ensuring optimal biological compatibility (proved with 20+ years of NovaBone history)

Did you know?

NovaBone is the originator of the FDA-cleared claim of Osteostimulation (2005).

Osteostimulation refers to the proven ability of Bioglass to activate genes which regulate osteoblast differentiation and proliferation

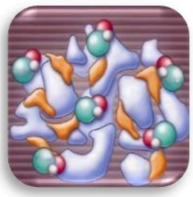
The Science:

The mechanisms of cell stimulation originate from cellular interactions with the ionic dissolution products released from NovaBone during its absorption.

Such interactions result in the up-regulation of several gene families associated with osteoblast activity.

How does it work?

Implantation & Ion Release



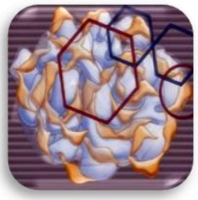
0-15 Minutes
Sodium, silicon, and calcium ions are released through surface dissolution; modified surface develops

Recruitment & Signaling



0-2 days
The ions recruit and signal osteoblasts to the modified surface to populate the scaffold of hydroxy-carbonate-apatite crystals

Proliferation & Differentiation



2-14 days
Osteoblasts proliferate and differentiate into cells that deposit mineralized extra-cellular matrices and osteocytes.

Osteostimulation



14+ Days
A rapid and complete regeneration of bone tissue takes place in the osseous defect

*Resorption times may vary by product type, defect size and patient conditions.

Clinical Case Report

NovaBone Bioglass Wedges in Evans & Cotton Osteotomies

NovaBone Products LLC. – Data on File

Surgeon: Dr. Charles E. Cook, M.D

Procedure: Evans & Cotton Osteotomies

Patients: N = 4 (75% female, 15-69 years of age)

Location: Dallas, TX (2024)

Overview:

In recent Evans and Cotton osteotomy procedures, Dr. Charles E. Cook, M.D. successfully corrected flatfoot in N = 4 patients (75% female, 15-69 years of age) with implantation of NovaBone® resorbable bioactive precontoured wedges at the osteotomy site.

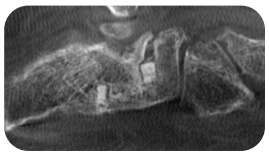
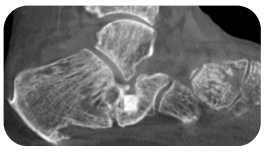
Dr. Cook optimized these procedures by performing the following:

· Adjusted the wedge size for a precise fit
· Enhanced healing by soaking the devices in growth factors
· Secured the wedges with resorbable staples

Results:

All 4 patients were successfully corrected using NovaBone® bioactive precontoured wedges. No adverse events have been reported.

Post-Op Imaging of all 4 patients at the most recent follow-up timepoint:

Patient 1 (standing CT)	Patient 2 (standing CT)	Patient 3 (standing CT)	Patient 4 (X-Ray)
			
12 weeks Post-Op	12 weeks Post-Op	12 weeks Post-Op	4 weeks Post-Op

Surgeon Statement:
Patient 1 “had allografts wedges on the right and Novabone on the left. The left had better correction due to the stronger Novabone wedges being able to achieve larger angled osteotomies.”

Key Takeaway:

These cases highlight the versatility and efficacy of NovaBone's bioactive precontoured wedges in foot & ankle osteotomy surgeries. The successful outcomes underscore the potential of these implants in enhancing surgical precision and promoting bone healing

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:

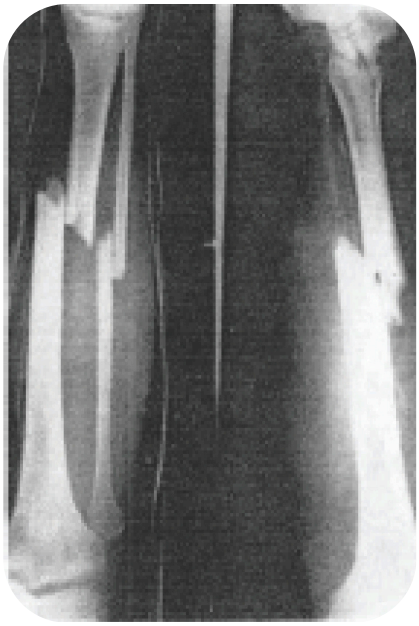
Tibial fractures are known to have long healing times and high rates of bone nonunion. Therefore the authors set out to expedite the healing rate of bone fractures and lower the rate of bone nonunion. In this study the author selected to use NovaBone Particulate to accelerate the healing process and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

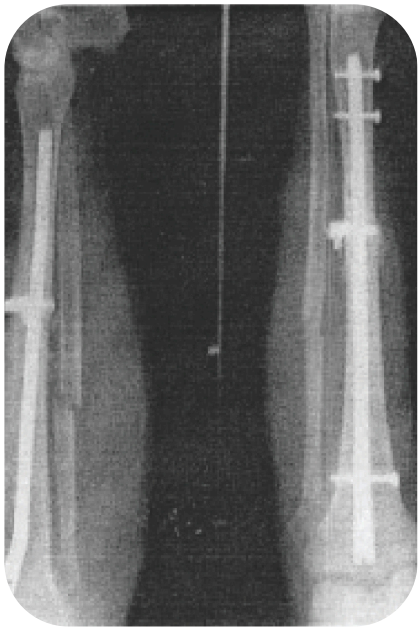
Method:

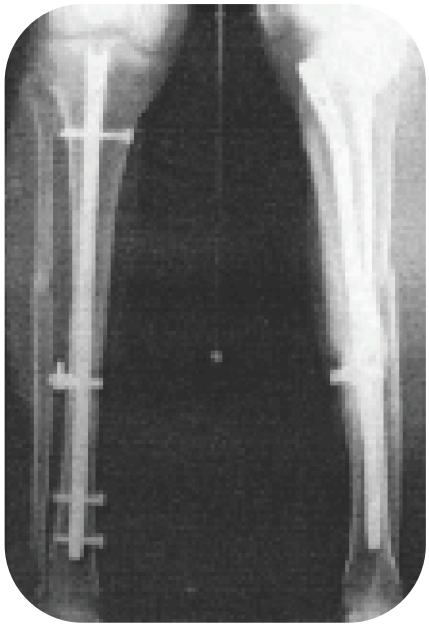
NovaBone was used in the experimental group in conjunction with open reduction and internal fixation of tibial fractures from March 2002-January 2003. A total of 78 patients were treated for fresh fracture of the tibia injuries, 47 Male Cases, 31 Female Cases, Ages 17-78 years old, Average Age 40.5 years 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 times 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 40 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.

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

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

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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)

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