

Clinical Trial Data Summary

For more information, contact your local representative,
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Orthofix Physio-Stim® Clinical Study

Purpose of the Study

Prospectively evaluate the safety and effectiveness of the Orthofix Physio-Stim Bone Growth Stimulator for fracture non-unions and failed arthrodeses.

Participants in the Study

This study was done nationally, with physicians affiliated with university, county, and community hospitals as well as Kaiser Permanente facilities.

Study Program

Study was conducted from September 1983 to July 1984.

Open Trial with patients who had not healed on their own after nine or more months. Patients served as their own controls.

Study population consisted of 181 patients with 193 fractures.

Independent panel of three Orthopedists reviewed all radiographs at the termination of treatment.

Success Criteria

The success of the treatment was measured both clinically and radiographically.

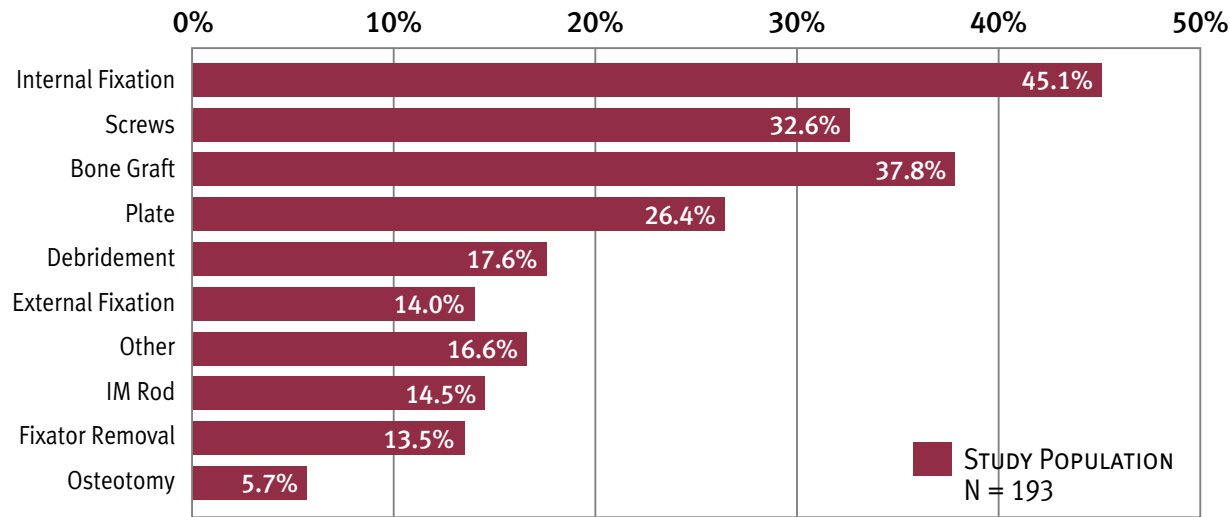
Clinical evidence criteria were:

At Fracture Site

1. No or Minimal Pain
2. No Motion
3. No or Mild Tenderness
4. No Casting

Type of Prior Surgical Procedures

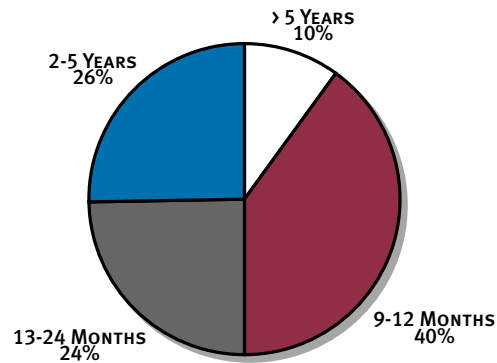
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Prior surgical intervention in 81% of the fractures with an average of 2 procedures per fracture

Fractures by Nonunion Duration

Average Duration Nonunion = 2.6 years



Success Rate by Fracture Site

Fracture Site	Success Rate
Ulna (n=10)	100.0%
Humerus (n=7)	100.0%
Femur, neck (n=2)	100.0%
Femur, other (n=13)	92.3%
Fibula (n=8)	87.5%
Radius (n=6)	83.3%
Metatarsal (n=5)	80.0%
Other (n=5)	80.0%
Scaphoid (n=13)	76.9%
Tibia (n=50)	74.0%
Fusion, other (n=6)	66.7%
Ankle Fusion (n=10)	60.0%

Success Rate

No statistical difference in success rates between the following:

- Open vs. closed fractures
- Disabilities of 9-12 month non-union compared with fracture non-unions of 1-10 years
- Age of patient (less than or greater than 60 years)
- Gender
- Infected vs. non-infected non-unions
- Fracture gaps up to 1 cm
- Long vs. short bone non-unions
- Weight bearing vs. non-weight bearing
- Daily treatment time > 3 hours/day
- 85% of patients were pain free at study conclusion

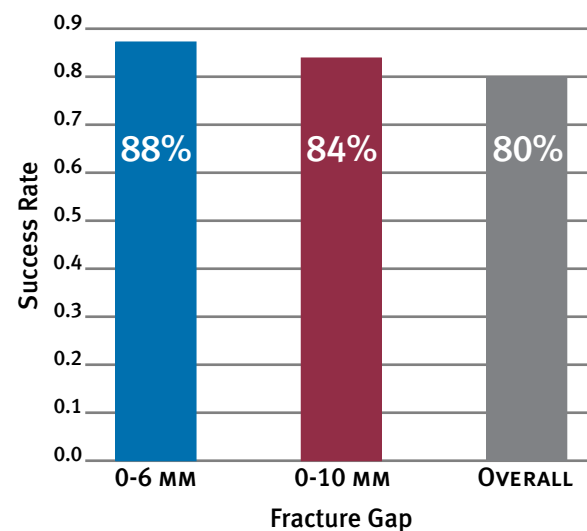
Long Term Follow-Up Results

No statistical difference between the four year success rate and the original success rate (Yates corrected Chi-square analysis).

No prognostic factors significantly impacted long-term success rates, nor were any long-term complications or adverse effects attributable to PEMF therapy reported by either subjects or physicians. For additional information, please see:

“Long-Term Follow-Up of Fracture Non-Unions Treated with PEMFs”, Douglas E. Garland, M.D., Barbara Moses, M.B.A., B.S.N., R.N., William Salyer, M.D.

Success Rates by Fracture Gap



For more information about Orthofix bone growth stimulators, call Orthofix Customer Service at (800) 535-4492



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