

Pre-Market and Post-Market Patient Registry Data

OL1000 Bone Growth Stimulator Post-Marketing Patient Registry Data

As of June 30, 1998, the OL1000 has been applied to 5300 patients with physician diagnosed nonunion with varying times from injury, 2 months or greater. Patient registry data was collected from December 1994 to December 1998. At the time of database closure, we expected follow-up on 4100 patients and received follow-up on 2370 patients (57.8%). Physician diagnosed healing determined patient outcome in the Patient Registry. The results of these 2370 patients are presented at right.

All patients were treated for 30-minutes per day and devices are programmed to provide a maximum of 270 days of treatment. The success rate in the pre-market clinical data was 60.7% and was maintained at 2 years post-treatment with 90% follow-up of all healed fractures. In the pre-market study, a nonunion was considered to be established when a minimum of nine months had elapsed since injury and the fracture site showed no visibly progressive signs of healing for a minimum of 3 months. Patient success was defined as three out of four cortices bridged on radiograph and no pain or motion at the fracture site.

By Site (Efficacy)	Healed #/Total # n/N	Outcome Rates	Average Heal Times (months)
Ankle	110/145	75.9%	4.7
Carpal Navicular	154/218	70.6%	3.9
Carpal/Metacarpal	35/39	89.7%	5.3
Clavicle	79/114	69.3%	5.1
Femur	160/250	64.0%	6.4
Fibula	58/68	85.3%	4.3
Humerus	103/180	57.2%	5.5
Metatarsal	408/477	85.5%	3.8
Phalanx (Finger)	21/24	87.5%	3.4
Phalanx (Toe)	22/29	75.9%	3.7
Radius	81/96	84.4%	5.0
Radius/Ulna	14/17	82.4%	5.3
Tarsal	51/77	66.2%	4.3
Tibia	285/372	76.6%	6.2
Tibia/Fibula	122/154	79.2%	5.8
Ulna	77/110	70.0%	5.0
Totals	1780/2370	75.1% Overall Outcome Rate	4.9 Weighted Average Time to Heal

OL1000 Bone Growth Stimulator Pre-Market Data

Time From Injury Comparison

Pre-Market Data

Average Time from injury

29.3 months

Median time from injury

18.3 months

Post-Market Registry

Average Time from injury

15.1 months

Median time from injury

6.3 months

By Site (Efficacy)	Healed #/Total # n/N	Success Rates	Average Heal Times (months)
Tibia	31/41	76%	5.8
Metatarsal	1/1	100%	4.0
Femur	5/13	38%	8.0
Carpal Navicular	4/12	33%	5.0
Humerus	2/4	50%	5.0
Ankle	1/1	100%	8.0
Radius	0/1	0%	NA
Ulna	4/5	80%	5.8
Fibula	1/4	25%	7.0
Metacarpal	1/1	100%	4.0
Capitate	1/1	100%	8.0
Totals	51/84	60.7% Overall Success Rate	6.0 Weighted Average Time to Heal

For indications and brief prescribing information, check the "Problem Healing Fractures" section within the Medical Professionals link of this website.