

Issues in pediatric fracture management

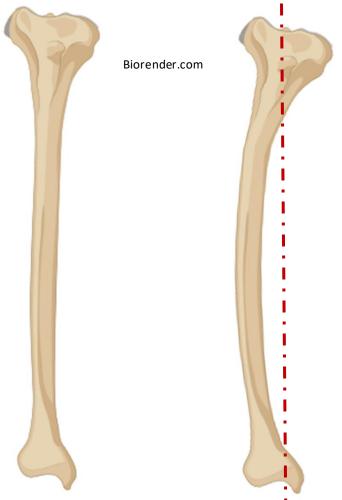
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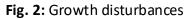
EPTRI Scientific Meeting 2025–Bologna, Italy – 14 Mar 2025

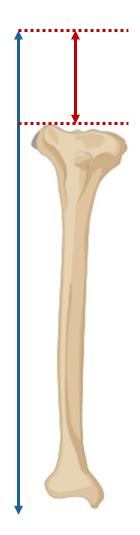
Growth Disturbances



Fig. 1: Growth plates









Bioresorbable Implants

Fig. 3: ZX00 implants



Pros



- ✓ no need for removal surgery
- ✓ Young's modulus closer to the one of bone
- less risk of stress shielding
- ✓ gradual load transfer promotes natural bone remodelling
- ✓ improved healing stimulation (especially Mg-based implants)
- ✓ reduced long-term complications

Cons



X lower mechanical strength – might not be sufficient for load bearing applications

Xlimited long-term data

X unpredictable degradation rates

X gas pockets formation



Recent Weinberg group studies:

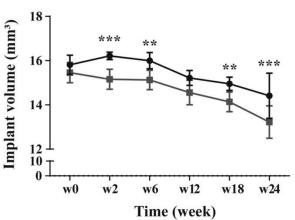
- Okutan B *et al*, The combined effect of zinc and calcium on the biodegradation of ultrahigh-purity magnesium implants. Biomater Adv. 2023 Mar;146:213287. doi: 10.1016/j.bioadv.2023.213287
- Marek R *et al*, Degradation behavior and osseointegration of Mg-Zn-Ca screws in different bone regions of growing sheep: a pilot study. Regen Biomater. 2022 Oct 18;10:rbac077. doi: 10.1093/rb/rbac077
- Marek R et al, Effect of ZX00 implantation through growth plate in growing sheep model, unpublished data
- Suljevic O *et al*, Osseointegration and biocompatibility of Ti, PLGA and ZX00 implants in sheep model, unpublished data
- Szyszko Mertelseder I *et al*, Comparative Evaluation of WE43 and ZX00 Magnesium Alloys for Fracture Fixation: Insights into Degradation Behavior, Biocompatibility, and Healing Outcomes in Sheep Model, unpublished data

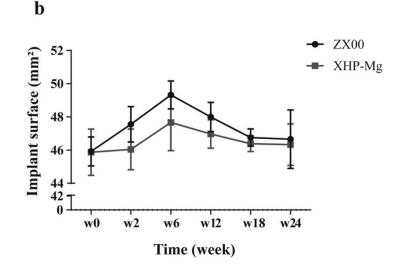


Degradation Rate

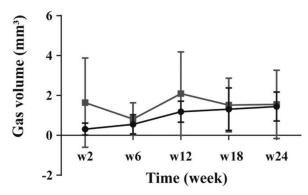
Fig 4. Quantification of the degradation performance of implanted ZX00 and XHP-MG over 24 weeks

a







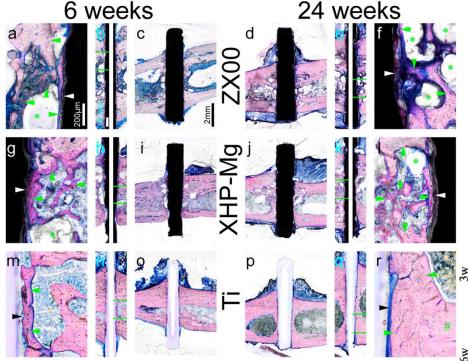


Okutan B et al, Biomater Adv. 2023 Mar

- ZX00 alloy (Mg-Ca-Zn) is more resistant to degradation
- ZX00 causes less gas accumulation that XHP-Mg



Fig 5. Representative images of Levai-Laczko-stained rat bone sections at 6- and 24-weeks post operation

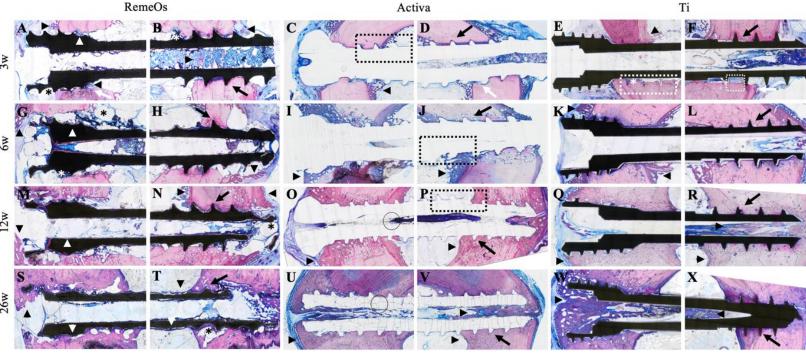


Okutan B et al, Biomater Adv. 2023 Mar

Bone Histology

- No signs of implantation-related inflammation
- Ti: attachment to the bone seems weak implant detachment during processing, soft tissue layer
- PLGA: deformations and cracking visible
- **ZX00:** less direct bone contact to implant due to faster degradation compared to PLGA, bone in contact with degradation layer

Fig 6. Representative images of Levai-Laczko-stained sheep bone sections at 3-, 6-, 12-, and 26-weeks post operation

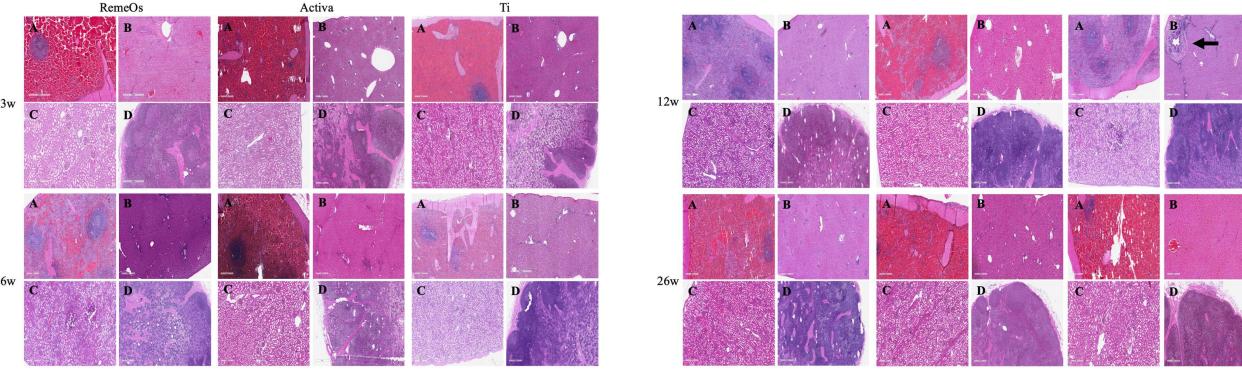


Suljevic O et al, unpublished data



Organ Histology

Fig 7. Representative images of Hematoxylin-Eoisin-stained sheep organ sections (A – spleen, B – liver, C- kidney, D – lymph node) at 3-, 6-, 12-, and 26-weeks post operation



Suljevic O et al, unpublished data

- No changes in architecture of the organs
- No signs of implantation-related inflammation
- No deposits of degradation products
- Black arrow: inflammation in bile duct associated with parasite infestation



Implantation through growth plate:
6 weeks post surgery

Fig. 8: Physis area at 6 weeks post-implantation

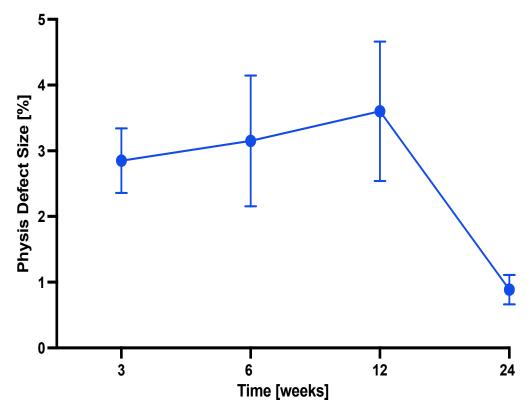




Marek R et al, unpublished data

Implantation through growth plate: Defect Size Evolution

Fig. 9: Physis defect size in relation to whole physis area at 3-, 6-, 12- and 24-weeks after implantation with ZX00 screws.



Marek R et al, unpublished data

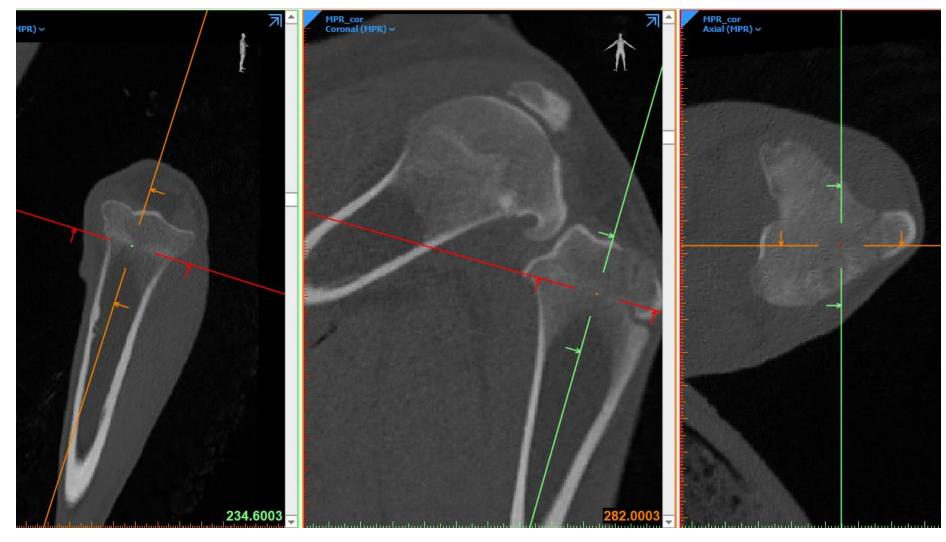
- Physis defect size initially grows due to gas accumulation
- Between 12- and 24-weeks post implantation there is rapid decrease in physis defect size



Implantation through growth plate: 52 weeks post surgery

✓ physis defect not visible at 52 weeks

Fig. 10: Physis area at 52 weeks post-implantation



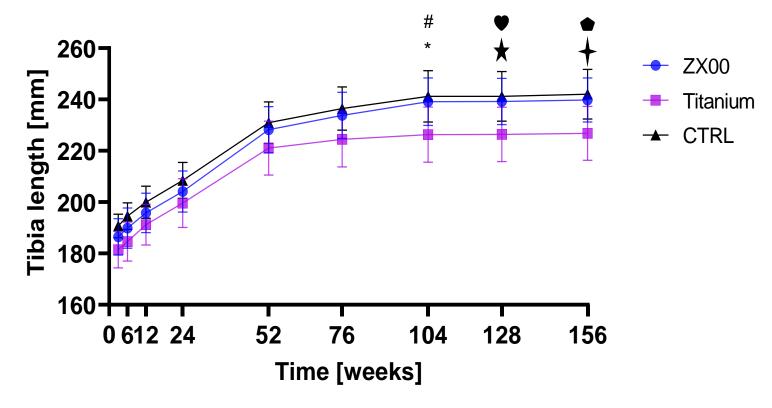


Marek R et al, unpublished data

Implantation through growth plate: Leg Length

- ZX00 and Control: no statistically significant difference in limb length up until skeleton maturity
- Ti: significantly shorter than ZX00 and Control starting at 104-weeks post surgery

Fig. 11: Tibia length up to 156 weeks after implantation.



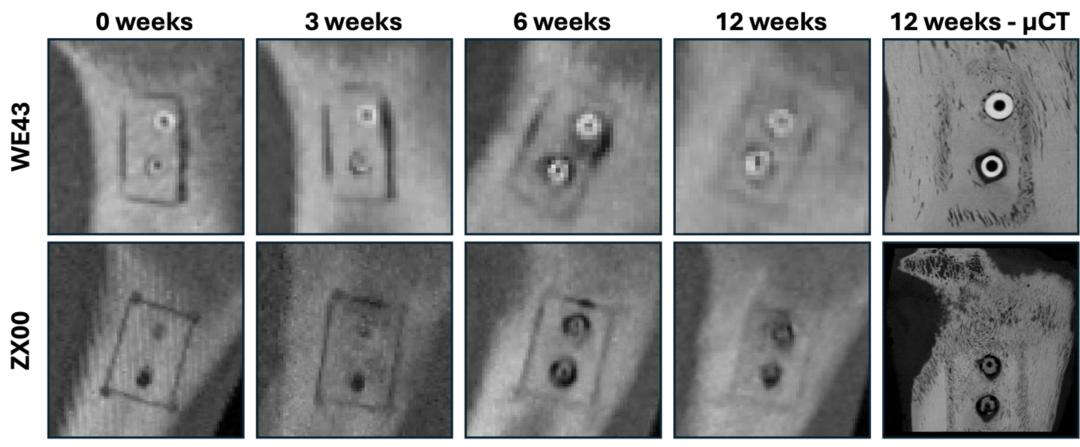
* p = 0.0434; indicates significance between Ti and ZX00 # p = 0.0421; indicates significance between Ti and CTRL ★ p = 0.0429; indicates significance between Ti and ZX00 ♥ p = 0.0429; indicates significance between Ti and CTRL ★ p = 0.0404; indicates significance between Ti and ZX00 ● p = 0.0356; indicates significance between Ti and CTRL

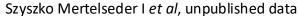
Marek R et al, unpublished data



Fracture healing

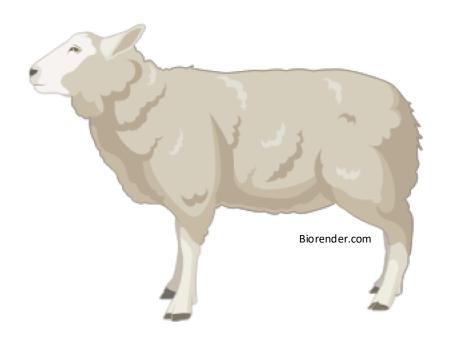
Fig. 12: Comparison of fracture healing evolution between two Mg-based alloys implanted in sheep tibia







Conclusions:





Mg alloyed with Zn and Ca exhibits slower degradation rate than ultra pure Mg



ZX00 implants are biocompatible and do not cause adverse effect or inflammatory response in solid organs



ZX00 implants stimulate new bone formation and do not cause foreign body response



Animals implanted with ZX00 screws showed no leg length difference or axial deviation compared to control and in contrary to Titanium



Animals implanted with ZX00 screws show sufficient fracture healing after 12 weeks



Future Outlook





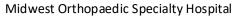
ZX00 screws available on the market with CE and FDA certifications



Mg-based K-wires being developed for the first time



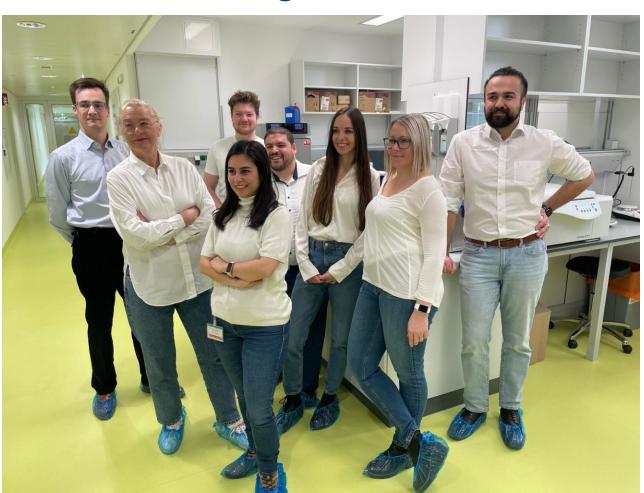
Clinical trial in children for distal radius fracture planned - foster healthier solutions in paediatric Ortho-Trauma care







Acknowledgements



Department of Orthopedics and Traumatology, MUG:

AG Weinberg: Annelie-Martina Weinberg,

Nicole Sommer, Begüm Okutan, Omer Suljevic, Romy Marek*, Christopher Stahle, Ilona Mertelseder, Nicole Zechmann, Sylvester Gabalier, Valentin Weigl, Haris Mujala, Patrick Ritchey

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Department of Dental Medicine and Oral Health, MUG:

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Department of Pathology, MUG: Iva Brcic

