Use of a Biodegradable Magnesium Implant for Osseous Fixation in Four Cases

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ABSTRACT

Due to excessive hydrogen gas production, early use of magnesium alloys as bone implants was abandoned despite good biocompatibility. Recently, studies revealed that magnesium alloys in vivo activated bone cells,2 with good biocompatibility and no harm to local tissues. In this study, there was no problem with Hydrogen gas production. The implants were very well tolerated, with no clinical signs of any problems. This may very well be the first research to monitor the degradation of magnesium beyond 6 months. The final radiographic images are intriguing. The implant within the bone has corroded, but even at 18 months, some of the magnesium alloy appears to still remain. Essentially, this study has apparently demonstrated that by specially treating the magnesium implant surface, the rate of corrosion is slowed significantly, and gas production is not recorded, thus eliminating the original reasons why magnesium implants were abandoned.

INTRODUCTION

Early use of Magnesium alloys as bone implants was abandoned because of excessive hydrogen gas production despite good biocompatibility[1]. More recent studies discovered that Magnesium alloys in vivo activated bone cells[2]. Furthermore there was good biocompatibility, with no harm demonstrated to local tissues from implanted Magnesium alloys[3]. The advantage of Magnesium (40 GPA) was that it has a similar modulus of elasticity to cancellous bone (10-30GPA) but the disadvantage was that it corroded too quickly loosing mechanical strength and producing Hydrogen gas at a rate of 1.08L per gram of Magnesium.

A study was undertaken to firstly analyse the mechanical strength of a Magnesium pin and also its behaviour following corrosion. The Magnesium alloy used in this study was chosen because it has already passed through clinical trials in human medicine[4-8]. Then four clinical cases were selected for fracture fixation using the biodegradable pins.

METHODS AND MATERIALS

The pins were specially treated after produc-

Table 1 *Signalement of cases*
Key
DSH- Domestic short hair
G Retriever- Golden retriever
CCLR- Cranial Cruciate Ligament rupture

Case	Age	Sex	Breed	Weight	Hydrogen gas production	Injury/ problem	Outcome
1	1year	F (n)	DSH	3.5Kg	0	Distal femur fracture	Excellent
2	4 yrs	F(n)	G Re-triever	35Kg	0	CCLR	Excellent
3	2yr	M(N)	Terrier	15 Kg	0	Fractured distal femur nonunion	excellent
4	8 yr	F(N)	Rottwei-ler	48 kg	0	CCLR	Excellent

tion by extrusion using chemically etching to produce a more corrosion resistive surface. Laboratory tested had confirmed that the pins lost mechanical strength over 30 days immersion in saline. Comparison between a 1.2mm diameter pin made of stainless steel and magnesium alloy revealed not dissimilar properties except in torsion were the magnesium alloy was significantly weaker. Because of this finding a method of insertion had to be worked out that allowed insertion into a bone without damaging the pin itself.

Following different trial insertion methods the method of choice was found to be to predrill a hole the exact same size as the Magnesium pin and then insert the pin at extremely low revolutions with no pressure applied. Using this method a Magnesium pin could be inserted into a bone sample. Once the technique of insertion had been optimised the implants were then used in actual clinical cases.

Four clinical cases where selected: fractured distal femurs in one dog (nonunion case) and one cat and 2 cranial cruciate deficient stifle repairs where the pins were used to fixate the tibial tuberosity. Each case was monitored weekly for any Hydrogen gas production.

RESULTS

The case details are summarised in Table 1. From the laboratory tests it was known that the mechanical properties of the material were reduced significantly with increasing immersion time. All cases healed uneventfully with no detection of hydrogen gas production. The magnesium pins were still visible although to a much less degree 18 months postoperatively on radiographs (Fig 1, 2, 3, 4, 5).

DISCUSSION

Corrosion and loss of material properties were clearly detected in the laboratory tests, which could be seen as a harsher than the biological environment. The Magnesium pins used in this study proved to be excellent bone implants apart from the very slow torsion resistance which made insertion delicate. In fact insertion of the pins was technically challenging to ensure avoidance of pin failure, and any other method apart from very slow drilling was possible for insertion.

There was no problem with Hydrogen gas production and this may reflect the small

Fig 1. Eight weeks postop TTA (Case 2)

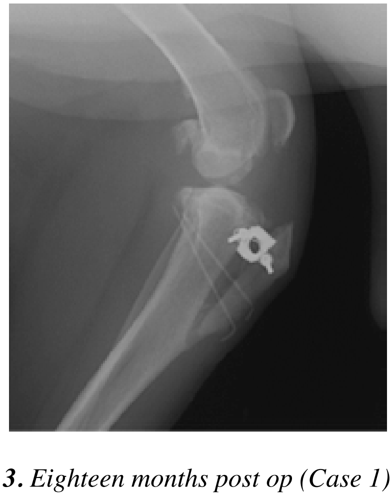


Fig 2. Post op femur fracture (Case 1)

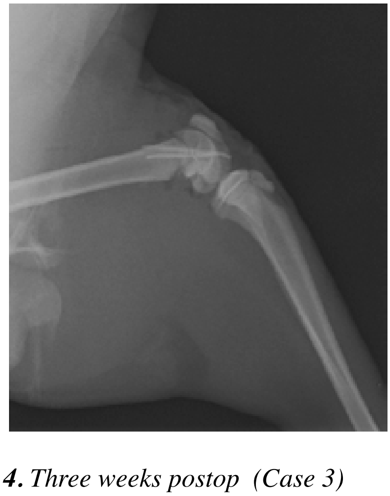


Fig 3. Eighteen months post op (Case 1)

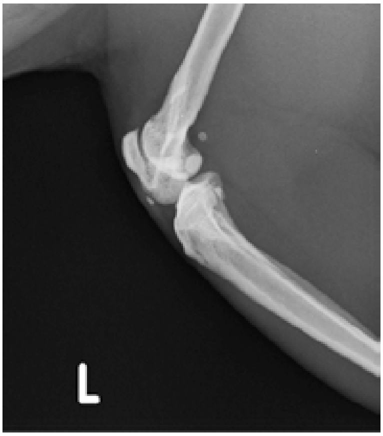


Fig 4. Three weeks postop (Case 3)

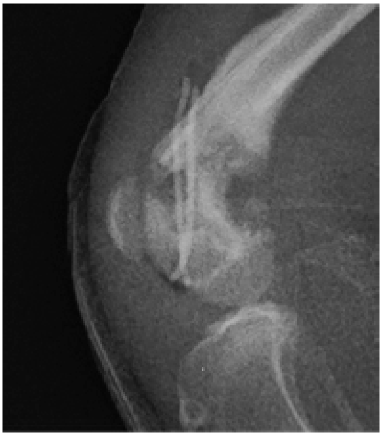
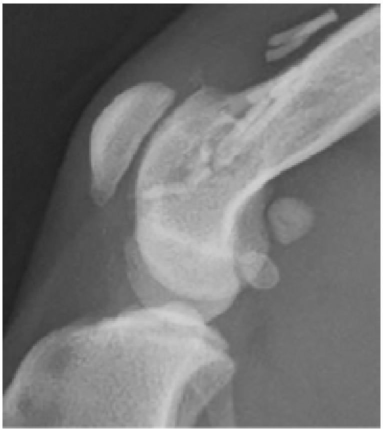


Fig 5. Eighteen months post op (Case 3)



size of the implants or surface treatment of the implant. The implants were very well tolerated with no clinical signs of any problems. The pins would have been expected to be 35% corroded by 6 months based on previous studies. No studies have been made beyond 6 months. Magnesium corrodes in a chloride environment usually by pitting corrosion and the production of Magnesium Hydroxide and Hydrogen gas. Magnesium has a very similar density to bone which may lead to difficult image interpretation. Also in other studies a concentration of Calcium and Phosphorus was noted in the degradation layer around the Magnesium implant. The local vascularity has a profound effect on the rate of degradation and in highly vascular areas the Magnesium will degrade quicker.

As this is to the author's best knowledge the first research to monitor the degradation of Magnesium beyond 6 months the final radiographic images are intriguing. The implant within the bone has corroded but even at 18 months some of the Magnesium alloy appears to still remain. This may in fact reflect reduced vascularity as the healing process comes to an end. Furthermore some of the outline of the implant may represent a concentration of calcium but this cannot be verified without sampling. Essentially this study has apparently demonstrated that by specially treating the Magnesium implant surface the rate of corrosion is slowed significantly and gas production is not recorded, thus eliminating the original reasons why magnesium implants were abandoned. The study has limitations in relation to fracture selection and case numbers, but the results are encouraging and warrant further investigation.

REFERENCES

1. McBride ED. Absorbable metal in bone surgery. *J Am Med Assoc*. 1938;111:27:2464-7
2. Witte F, Kaese V, Haferkamp H, Meyer-Lindenberg A, Wirth CJ, Windhagen H. In vivo corrosion of four magnesium alloys and the associated bone response. *Biomaterials*. 2005;26:3557-3563
3. Witte F, Ulrich H, Rudert M, Willbold E. Biodegradable magnesium scaffolds part 1: Appropriate inflammatory response. *J BioMed Mat Res*. 2007;81A:748-756
4. Galvin E., Cummins, C., Colombo, A., Lally, C., MacDonald, B.J., "In Vitro Corrosion Testing of Absorbable Magnesium Stents", Proceedings of the 28th International Manufacturing Conference, Dublin City University, September 2011.
5. Galvin, E., Cummins, C, Coleman, J., Mathews, D., Colombo, A., Lally, C., MacDonald, B.J., "An Experimental and Numerical Analysis of a Bioabsorbable Magnesium Alloy Cardiovascular Stent", Proceedings of the 26th International Manufacturing Conference, Trinity College Dublin, September 2009.
6. Galvin, E., MacDonald, B.J., "Explicit & Implicit Finite Element Analysis of a Bioabsorbable Magnesium Alloy Cardiovascular Stent", Proceedings of the Northern Ireland Biomedical Engineering Society Spring Conference, April 2009.
7. Galvin, E., MacDonald, B.J., "Experimental and Numerical Analysis of a Bioabsorbable Magnesium Alloy Cardiovascular Stent", Bioengineering In Ireland 15 Conference, Castletroy Park Hotel, Limerick, January 2009.
8. Galvin, E., MacDonald, B.J., "Finite Element Simulation of the Deployment of a Magnesium Cardiovascular Stent", Proceedings of the 25th International Manufacturing Conference, Dublin Institute of Technology, September 2008.