Osseointegration Of Polyethylene Implants Coated With A Thin Layer Of Titanium And Biomimetically Or Electrochemically Deposited Hydroxyapatite In A Rabbit Model

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Disclosures:

Introduction: Osseointegration remains a challenge in hip arthroplasty. In addition, the effects of modularity with metal-back acetabular components using polyethylene (PE) inserts could increase wear and therefore peri-prosthetic osteolysis with cementless fixation (1). The aim of this study was to evaluate osseointegration of a new coating directly deposited on PE at room temperature. The new coating was composed of a thin layer of titanium ionic plasma deposited (TiPVD) on PE and a second layer of hydroxyapatite (HA), deposited biomimetically or electrochemically. The hypothesis was that the new coating would provide comparable osseointegration of PE than metal-back cup, represented by a micro-rough titanium implant coated with plasma sprayed HA. Osseointegration was assessed by histomorphometric and biomechanical techniques in a rabbit model of osseointegration.

Methods: Thirty-six male, adult, New Zealand rabbits weighing 3.5 kgs were randomly assigned to receive one out of three types of cylindric implants (length 6mm; diameter 4mm): two tested implants, i.e. PE implant coated with either TiPVD and biomimetic HA (Biomimetics, BIO), or TiPVD and electrolytic HA (Electrolytic, ELE), and a plain micro-rough titanium coated with plasma sprayed HA (TiHAPS) used as positive control.

Osseointegration was evaluated by histomorphometry (bone tissue in contact (BIC), and mineralized bone area (MBA)) and mechanical testing (push-out test, interfacial shear strength (ISS)) in distal femur spongy bone samples at 6 and 12 weeks (figure 1 and 2).

Each rabbit was operated on both lower limbs during the same intervention. A total of 72 distal femurs were assigned to one of the implant types in order to obtain six samples per group and per testing method at each time point for analysis (2,3,4). Data are provided as the mean ± standard error of the mean. Non-parametric Mann-Whitney tests were used for analyzing the difference between groups at each time point. A p-value <0.05 was considered to indicate a significant difference.

The study was approved by the local governmental animal care committee and was conducted in accordance with the European guideline for care and use of laboratory animals.

Results: At 6 weeks, BIC values were 0.61 ±0.19, 0.65±0.13 and 0.65±0.12 for TiHAPS BIO and ELE implants, respectively and at 12 weeks, 0.63±0.18, 0.74±0.08, and 0.61±0.12 for TiHAPS, BIO and ELE, respectively. There was no significant difference between groups at 6 (p=0.98) and 12 weeks (p=0.13) (graph 1).

At 6 weeks, MBA values were 0.58±0.17, 0.59±0.07 and 0.65±0.11 for TiHAPS, BIO and ELE implants, respectively, and at 12 weeks, 0.53±0.18, 0.67±0.09 and 0.61±0.15 for TiHAPS, BIO and ELE implants, respectively (graph 2). No statistically difference was measured between groups at 6 (p=0.52) and 12 weeks (p=0.57).

At 6 weeks, ISS was 7.41±1.64, 4.01±1.53 and 4.14±1.57 MPa for TiHAPS, BIO and ELE implants, respectively. The difference was significant (p=0.01). At 12 weeks, ISS was 5.07±1.87, 5.33±2.61 and 4.66±1.63 MPa for TiHAPS, BIO and ELE implants, respectively. There was no significant difference between groups at 12 weeks (p=0.92) (graph 3).

Discussion: Histomorphometric data did not show any differences between implants for Bone tissue In Contact and Mineralized Bone Area between the 6 and 12-week time points, which could be interpreted on a histological standpoint, as if the initial mineralization was already almost complete at 6 weeks in this model. The histological difference between 6 and 12 weeks was mostly the development of a bone remodeling, more evident at 12 weeks. Bone remodeling has been described to increase up to 52 weeks in rabbits.

The only measurable difference between TiHAPS, Biomimetic and Electrolytic implants was a greater mean ISS value for TiHAPS implants on the push-out testing at 6 weeks. This difference was no longer apparent at 12 weeks. The coating combination of a thin titanium layer (Ti-PVD) and biomimetically or electrolytically deposited HA was therefore as good as a full metal titanium implant coated with plasma sprayed HA as regards the mechanical properties and the observable development of osseointegration at 12 weeks.

This study demonstrated that polyethylene implants coated with Ti PVD and biomimetically or electrolytically deposited HA were able to develop efficient and solid osseointegration, comparable to that of plasma sprayed-HA coated titanium.
Significance: These implants could theoretically prevent the complications related to modularity including backside wear. While the present results are encouraging, it is too early to conclude from this 12 week study whether the tested combinations will enable the efficient and solid fixation of PE implants without the use of cement and metal back acetabular cups in the clinical practice.

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References:

Figure 1: histomorphometry. A: Measure of mineralized bone in contact in 100 μm around the implant. B: Bone in contact, sum of all α angles.
Figure 2: push-out test, 0.5 mm/min, Interfacial Shear Strength (ISS) measurement

ISS = maximal measured strength (Newton)

\[ \pi \times \text{Diameter (mm)} \times \text{Length (mm)} \]
Graphic 1: Bone in contact, expressed in angle rapport.
Graphic 2: Mineralized bone area, expressed in area rapport.
Graphic 3: Interfacial Shear Strength expressed in Mpa at 6 (in blue) and 12 (in red) weeks

*p < 0.05