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Low metallic wear of dynamic intraligamentary stabilization

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ABSTRACT

Dynamic Intraligamentary Stabilization (DIS) represents a treatment option for acute anterior cruciate ligament ruptures. The device used for DIS consists of a polyethylene braid and a metallic spring system, allowing the remnants of the ligament to recombine in a stabilized position over the self-healing period. This work addresses the metallic wear generated thereby. A cadaveric study was carried out with n=8 knees over 50'000 cycles, along with a control group to validate the cleaning and assembly process. Gravimetric analysis yielded a total wear of (0.28 ± 0.35)mg for the entire implant. 50% of the wear originated from the bush and 46% from the clamping element. In a worst case scenario, a total wear of 1.7 mg would result during the functional lifetime.

1. Introduction

Anterior cruciate ligament (ACL) ruptures constitute a considerable health issue with an annual incidence rate of reconstruction surgeries estimated between 34 and 44 per 100'000 people in western countries [1–4]. In 2009, the Dynamic Intraligamentary Stabilization (DIS) was introduced, allowing for the treatment of acute ACL ruptures if treated within the first 21 days after injury [5]. The Ligamys device used for DIS couples a polyethylene braid to a metallic spring system (illustrated in Fig. 1), preventing the tibia from subluxation to a neutral position [6]. After the ligament has stably healed and taken over its function again, the tibial component of the implant can be removed. This takes place in approximately one quarter of the cases for medical reasons or personal choice [7]. In the mean time, five year results concerning the function of this device are available [8,9].

Metal release in the human body is of particular interest because several complications can arise, such as pseudotumors with hip implants [10] and harmful effects on immunity, reproduction, the kidney, developmental toxicity, the nervous system and carcinogenesis [11]. Especially Cr, Ni andCo – which are contained in the spring – can generate reactive oxygen species which may induce oxidative DNA damage [12,13]. The aim of this investigation therefore was to measure the metallic wear generated in the Ligamys implant over a simulated rehabilitation period of 50'000 gait cycles. The test was limited to 50'000 cycles because prolonged cadaveric studies suffer from degradation of mechanical properties and odor nuisance. For the general healthy population, 50'000 cycles would correspond to approximately 10 days of normal activity [14]; however for the post-operative situation it corresponds to a much longer period as activity is ramped up slowly according to the rehabilitation protocol (4 days of knee immobilisation followed by a step by step resumption of normal physical activity).

2. Material and methods

The DIS device consists of four metallic parts: a threaded bush which is implanted into the tibial head, a spring, a clamping element that slides inside the bush and displaces the spring, and a cone which fixates the braid to the clamping element (see Fig. 1). The spring consists of a cobalt-chromium-nickel alloy (ISO 5832-7), while all other components are made of stainless steel (ISO 5832-1).

In total, 13 implants were used for this study. Eight implants were implanted in human cadaveric knees for dynamic testing under physiological conditions, while five implants served as control group. The control group was cleaned, immersed in test liquid for 24 h, cleaned again and weighed in order to validate the cleaning process especially with regards to protein removal because the weight of proteins remaining on the surface would invalidate the gravimetric analysis. Afterwards, the components of the control group were assembled and disassembled, cleaned again and weighed again to quantify the assembly/disassembly contribution to the overall mass loss. The assembly/disassembly contribution was defined as the mass

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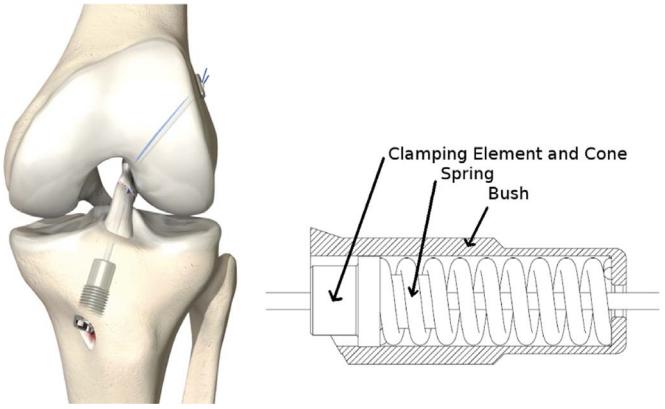

Fig. 1. Illustration of the Dynamic Intraligamentary Stabilization, reproduced from http://www.ligamys.com: Overview of the implanted device (left) and cut with individual components (right). During assembly, the cone is inserted into the clamping element, clamping the braid in between.

difference between the time points after final cleaning and immediately before the assembly/disassembly procedure.

The test liquid was based on bovine serum (newborn calf serum, New Zealand, GIBCO Invitrogen Corporation, Lot 8097790) which was diluted with deionized water to a protein concentration of 30 g/L according to ISO 14242–1:2014. 2 g/L sodium azide and 3 g/L EDTA were added to inhibit bacterial growth and to bind metallic ions, respectively. The test liquid was filtered with 0.2 µm filters, stored at −20 °C and thawed before application. Diluted newborn calf serum is widely used as simulation liquid for the synovia in hip joint simulators [15]. The same test liquid was also used in the cadaveric part of the study for irrigation purposes.

For the gravimetric analysis, the individual components were weighed on an electronic scale (XS 205, Mettler Toledo, Columbus, OH, USA) with a precision of 0.01 mg. Prior to weighing, they were cleaned according to a standardized cleaning process consisting of the following steps: 10 min cleaning in deionized water in an ultrasonic bath, rinsing with deionized water, 10 min cleaning in deionized water with Deconex detergent (Borer Chemie AG, Zuchwil, Switzerland) and rinsing in deionized water. Thereafter, 10 min cleaning in deionized water in an ultrasonic bath, rinsing with deionized water, 3 min cleaning in deionized water in an ultrasonic bath, rinsing with isopropanol, and finally 5 min drying under cold air stream. Subsequently, all components were weighed twice in the same order and the average value was recorded.

For the cadaveric tests, eight fresh-frozen human cadaveric knees (four pairs, 25–40 years, BMI 17–25) were harvested and thawed at room temperature 24 h prior to implantation. All DIS devices (Art. No. 82.34.0013 and 82.34.0005, Mathys Ltd. Bettlach, Switzerland) were implanted by the same experienced surgeon (PH) using the respective standard instruments. In order to achieve alignment of the interwoven fibers, preloading of the braid with 300 N was performed prior to its fixation at a tension of 80 N at a knee flexion angle of 10°. A machine actuator (MTS 858 Bionix, MTS Systems Corp, Eden Prairie, MN, USA) was used to achieve cyclic flexion and extension of the knee between 0° and 70° at a frequency of 1 Hz [16]. During the test duration of 50'000 gait cycles, an irrigation system provided lubrication with test liquid.

After testing, the implants were explanted and subjected to the cleaning and weighing protocol. The results of this weighing procedure were corrected for the cleaning contribution as described above, therefore they represent the worst case mass loss.

Statistical analysis was performed with the software package R version 3.1.1 [17,18] at a significance level of 0.05, probing whether the mean mass change is different from zero. All groups were tested for normality of distribution using the Shapiro-Wilk test. Normality was rejected for the bush control group before immersion in test liquid, after cleaning and after assembly/disassembly (p=0.04 for all). Therefore, the Wilcoxon Signed Rank test was chosen to screen the statistical significance among all groups.

Table 1
Mean measured mass changes Δm in mg and p values of the cleaning control group (n=5). Negative values denote mass losses, while positive values represent mass gains. None of the values of the control group were assessed as statistically significant.

Cleaning control group	Mass change mean Δm [mg]	Mass change std. dev. σ_m [mg]	Relative mass change [ppm]	p value
Clamping element	0.02	0.01	8	0.058
Spring	0.03	0.02	11	0.063
Cone	0.05	0.02	73	0.063
Bush	0.03	0.08	5	0.586

3. Results

The immersion in test liquid for 24 h and subsequent cleaning yielded mass gains between 0.02 mg and 0.05 mg (Table 1). It did not reveal a significant mass change for any component (clamping element: p=0.058; spring: p=0.063; cone: p=0.063; bush: p=0.586). Especially the bush showed a higher standard deviation than the mean value and was therefore clearly not significant. The high standard deviation however has to be considered in perspective to the relatively higher mass of the component.

All mass changes attributed to the assembly and disassembly process were between a gain of 0.01 mg and a loss of 0.02 mg (Table 2). No statistically significant changes were detected due to the assembly and disassembly process for any of the components (clamping element: p=0.100; spring: p=0.058; cone: p=0.313; bush: p=0.625). For the cone and especially for the bush, the standard error exceeded the mean value and was therefore clearly not significant.

In the group with implants explanted from the cadaveric tests, one clamping element was dropped to the floor and excluded, therefore the number of evaluated samples for the clamping elements was reduced to n=7. Furthermore, there were two outliers in the group of the cones, one with a mass gain of 0.28 mg (due to adsorbed tissue) and one with a mass loss of 1.93 mg, two orders of magnitude above the other samples. Visual inspection revealed that the mass loss could be traced back to damage to the interior wall caused during disassembly (Fig. 2). Thereby, the number of samples was reduced to n=6 for the clamping cones. Additionally, one outlier was removed in the bush group because overly damaged interior walls were visible, most likely due to excessive force during explantation, reducing the number of samples to n=7. Wear from regular operation and explantation create distinct characteristic patterns (see Fig. 3). Box plots of these results are shown in Figs. 4 and 5. The spring, cone and bush did not exhibit a statistically significant mass change (p=0.20, p=0.25 and p=0.47, respectively). The only significant mass change was detected for the clamping element (p=0.022) as listed in Table 3.

Table 2
Mean measured mass changes Δm in mg and p values of the assembly control group (n=5). Negative values denote mass losses, while positive values represent mass gains. None of the values of the control group were assessed as statistically significant.

Assembly control group	Mass change mean Δm [mg]	Mass change std. dev. σ_m [mg]	Relative mass change [ppm]	p value
Clamping element	−0.01	0.01	−6	0.100
Spring	0.01	0.01	4	0.058
Cone	−0.02	0.03	−25	0.313
Bush	0.00	0.09	0	0.625