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In vitro properties of PLLA screws and novel bioabsorbable implant with elastic nucleus to replace intervertebral disc

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The suitability of two different implant types for the replacement of the intervertebral disc was studied *in vitro*. Self-reinforced poly-L-lactide (SR-PLLA) screws Ø 4.5 mm were studied 24 weeks *in vitro* and cylindrical implants with elastic nucleus made of poly(L/D)lactide 96/4, poly(L/DL)lactide 70/30, Bioactive Glass n:o 13–93 and Polyactive® 1000PEOT70PBT30 were studied 15 weeks *in vitro*. The cylindrical implant mimics the size and shape of the intervertebral disc. During the *in vitro,* there were no changes in compression properties with either implant types. The screws had sufficient modulus for intervertebral ossification in the canine model and the cylindrical implant showed also sufficient mechanical properties. These results suggest that both implant types could be used in clinical testing.

1. Introduction

The human spine has 26 vertebrae: cervical (neck) 7 vertebrae C1-C7, thoracic (chest) 12 vertebrae T1-T12, lumbar (back) 5 vertebrae, sacral 1 (5 fused) vertebrae and coccygeal 1 (3 to 5 fused) vertebrae. Vertebrae are separated with intervertebral discs which are cushion-like pads acting as shock absorbers. The discs have strong outer ring of fibrocartilage (annulus fibrosus) and inner semi-fluid (nucleus pulposus). The annulus fibrosus also holds together the adjacent vertebrae [1].

Heavy loads subjected to the spine are transformed to the intervertebral discs possibly causing prominence, neural compression and/or rupture of the disc. Also degenerative diseases and aging may damage the intervertebral discs [2]. A frequently used method for repairing a ruptured disc is called spinal fusion. The damaged disc is removed and replaced with a bone graft, or a fusion devise, that fuses the adjacent vertebrae together [3]. The system or adjacent vertebrae is usually stabilized with metal plates and screws. Undesirable effects in long term use and graft-related construct failures have been reported [4, 5]. Different implant types such as total artificial disc replacement implants and nucleus substitute implants have been studied. Only few bioabsorbable implants are commercially available and usually metal implants or bone-grafts are being used [6, 7]. Composite hydrogels, hydroxyapatite, calcium phosphate grafts and composites and other artificial discs have been studied for spinal fusion due to their bone bonding abilities [6, 8–10]. The surface-treated bioactive glass has been shown to serve as surface that nucleus pulposus cells can attach, proliferate and maintain their phenotype [11]. The modern approach would be focused on retaining the motion of the spine instead of fusing the vertebrae together by replacing the intervertebral disc and still maintain the stability and flexibility of the spine.

The ruptured intervertebral disc can be removed and replaced using two surgical approaches, the posterior and the anterior approach. The benefit of the posterior instrumentation is that it is very strong and rigid. The main disadvantage is that it often requires the detachment of the spinal muscles and some complications may occur as the surgeon has to disrupt the facet joints. In the anterior approach the procedure is done entirely from the front. Complications associated with posterior approach may be avoided. Yet some complications such as vascular injury may occur [12].

In clinical findings the anterior interbody fusion has better outcome than the posteolateral fusion with internal fixation, but there is higher rate of fusion in the posteolateral group [12, 13].

The aim of the current work was to estimate the suitability of two different types of spinal implants. Bioabsorbable Self-Reinforced Poly-L-lactide (SR-PLLA) screws and novel bioabsorbable intervertebral disc implants with elastic core were put to *in vitro* and tested for mechanical properties, weight changes, molecular weight changes and thermal properties. The SR-PLLA screws have been successfully used in orthopaedic surgery [14]. For this study the new type of disc implant with elastic core is considered as a fusion device but in the future we hope it could, with minor modifications such as nucleus pulposus cell cultivation, be used to replace the function of the original intervertebral disc. Clinically two screws are intended to be screwed

parallel between two vertebrae in anterior-posterior direction and the screw heads then removed. Two screws are placed side by side so that they support each other in bending, flexion and torsion thus making the system stable. The cavity between the screws will be filled with crushed bone. Both implant types are considered to be placed using anterior fixation approach.

2. Materials and methods

2.1. Implants and screws

2.1.1. Cylindrical composite implants

The implant was a composite with elastic core surrounded by matrix and reinforcement material as seen in Fig. 1.

Core polymer was Polyactive® 1000PEOT70PBT30 (segmented block copolymer of poly(ethylene oxide terephtalate)/poly(butylene terephtalate) with PEOT/PBT ratio being 70/30). The molecular weight of the copolymer was 80,000–125,000 dl g^{-1} (copolymer was supplied by IsoTis BV, Bilthoven, The Netherlands). The copolymer was mixed in the Gimac Ø 12 mm single screw microextruder (Gimac, Gastronno, Italy) with bioactive glass 13-93 particles (consisting of 6 wt% Na_2O, 12 wt% K_2O, 5 wt% MgO, 20 wt% CaO, 4 wt% P_2O_5 and 53 wt% SiO_2, Abmin Technologies Ltd., Turku, Finland). The crushed and milled bioactive glass particles were sieved to particle distribution 50–125 μm. Both the raw polymer and the polymer/glass composition was then separately extruded through a round die, average diameter of the produced rod being 3.7 mm and average content of glass in the composite being 23 wt%. The rods were cut to the lengths of 5 mm.

Matrix material was a mixture of 15 wt% of medical grade poly(L/DL)lactide 70/30 (RESOMER® LR 708, Boehringer Ingelheim, Germany, inherent viscosity 6.1 dl g^{-1}) and 85 wt% of bioactive glass 13–93 (same as above). The polymer was dissolved in acetone (ratio of the polymer/acetone was 2 g/30 ml) and the bioactive glass was mixed to it to form a paste-like mixture.

Matrix reinforcement material was medical grade poly(L/D)lactide 96/4 (PURAC biochem bv, Gorinchem, The Netherlands, inherent viscosity of 5.47 dl g^{-1}) that was melt-spun (Gimac microextruder, Gimac, Gastronno, Italy) to fibres using nozzle with 8 orifices (single orifice diameter 0.4 mm) and oriented using laboratory scale orientation line to the draw ratio 4.2. The multifilament fibre was knitted to a tubular single jersey knit and 300 mm long pieces of the knit was used in each implant.

When combining the components the matrix paste was thoroughly spread on to the PLA96-knit. The combination of knit and matrix was rolled around Polyactive + bioactive glass composite rods that formed the elastic core of the implant. The implant was heat-treated in a mould at 80 °C for 1 h, cooled down to room temperature and removed from the mould. The cylindrical implants were packed and gamma irradiated for sterilization (25 kGy).

Nine reference series ($n = 3$) were made (Table I). All the reference series samples were gamma-sterilised.

TABLE I Compositions of the 9 reference series

	Core material	Matrix material	Matrix reinforcement knit
Set 1	–	[c]	poly(L/D)lactide 96/4
Set 2	–	poly(L/DL)lactide 70/30	poly(L/D)lactide 96/4
Set 3	–	poly(L/DL)lactide 70/30 + BG 13-93	poly(L/D)lactide 96/4
Set 4	Polyactive[a]	[c]	poly(L/D)lactide 96/4
Set 5	Polyactive	poly(L/DL)lactide 70/30	poly(L/D)lactide 96/4
Set 6	Polyactive	poly(L/DL)lactide 70/30 + BG 13-93	poly(L/D)lactide 96/4
Set 7	Polyactive + BG 13–93	[c]	poly(L/D)lactide 96/4
Set 8	Polyactive + BG 13–93	poly(L/DL)lactide 70/30	poly(L/D)lactide 96/4
Set 9[b]	Polyactive + BG 13–93	poly(L/DL)lactide 70/30 + BG 13-93	poly(L/D)lactide 96/4

[a]Extruded Polyactive rod.
[b]*In vitro* composition.
[c]When matrix material was not used the end of the knit was attached to the knit roll with poly(L/DL)lactide 70/30 dissolved in acetone.

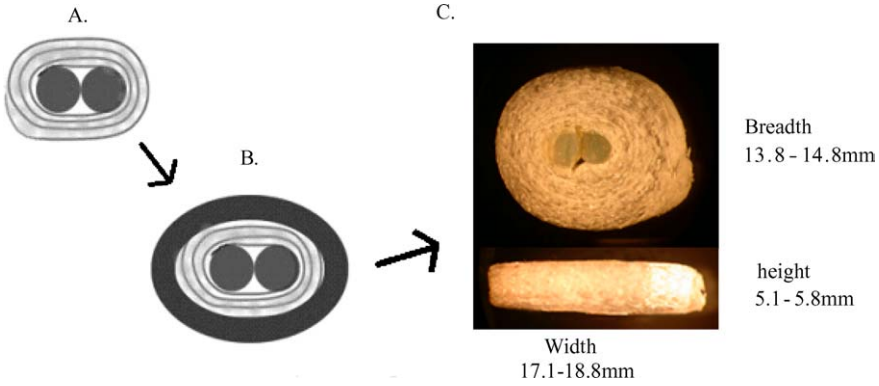

Figure 1 (A) The reinforcement was rolled over the core rods and (B) placed in to the mould. The composite was heat-treated and the mould was (C) removed to form the implant.

2.1.2. Screws

Three different types of gamma-sterilised screws with diameter of 4.5 mm were used (BIOFIX, Bionx Implants Ltd., Tampere, Finland):

(1) Self-reinforced poly-L-lactide, SR-PLLA, screws,
(2) SR-PLLA cannulated screws,
(3) SR-PLLA cannulated screw with intramedullary rod filling in the cannula of the screw.

12 mm pieces from the threaded part of the screws were cut from them and used for mechanical testing. Cut-offs from the screws were used for other studies.

2.2. Mechanical testing

All the tested samples were compressed at a rate of 1 mm min^{-1} between parallel polished steel plates using LLOYD LR 30 K mechanical testing machine (Lloyd Instruments Ltd., Fareham, England). All tested sets had three parallel samples and results are given as averages with standard deviations.

Cylindrical implants were intended for separate use and thus they were tested one at a time. The implants were compressed up to 9.3 kN between the compression plates. The compression modulus (E_c) of the implants was calculated using the formula

$$E_c = \delta/\varepsilon = (\Delta F/A)/(\Delta h/h) \quad (1)$$

where ΔF was the change in load, A was the area of the implant, Δh was the change in extension with corresponding load ΔF, and h was the height of the implant. Because the implants were hand made they were not symmetric ellipses. The area calculated for the ellipse would have been smaller than the actual area, therefore the area was calculated as an average circular area,

$$A = \pi((\text{width} + \text{breadth})/4)^2 \quad (2)$$

this was better estimation of the area. Also the porosity of the implant was not taken into account. The same area was used to calculate the compression stress in different points in the axis. The stiffness was calculated by linear regression from the load-compression curve.

$$\text{Stiffness} = \Delta F/\Delta h \quad (3)$$

Compression test of the screws was performed by testing two parallel 12 mm pieces of screws simultaneously in order to simulate the implantation situation. The screws were compressed to 9.5 kN and the modulus was calculated from the linear part of the curve using the Equation 1. The area used for Equation 1 is in Equation 4

$$A = \{A_2(\text{area at } h_2) + A_1(\text{area at } h_1\}/2 \quad (4)$$

While pressing the screws the area is changing from 0 to 108 mm^2 (hypothetic area if the screws are compressed flat without a change in diameter). To simplify the calculations two extension points ($h_1 = 0.35$ mm and $h_2 = 0.61$ mm) were chosen at linear part of the curves. Thus the average area that was used in the modulus calculus was 48 mm^2. The actual area is significantly smaller because only the threads of the screws are compressed at first thus the actual modulus of the threads is higher than the calculated modulus.

Both the cylindrical implants (set 9) and solid SR-PLLA (type 1) screws were tested wet at indicated periods *in vitro* in a similar manner, except the 0-week cylindrical implants and the reference series were immersed in purified water for 1 h prior testing whereas the 0-week screws were tested dry. The Polyactive + BG rods swelled up during the *in vitro*, this affected the compression curve so that the pressure from 0 to 2 kN was only the compression of the rods, this was also visibly noted. To measure the modulus and stiffness for the whole implant the Δh in compression modulus and the stiffness was measured between 2 and 3 kN from the curve, ΔF being 1 kN.

2.3. *In vitro* procedure

The gamma-sterilized cylindrical implants were immersed in a phosphate buffer solution (PBS, pH 7.4 ± 0.2) and held at 37 °C for periods of 1, 6, 12 and 15 weeks. The samples were individually incubated in buffer solution, solution to mass ratio being ~70 ml g^{-1}. Every 2 weeks the buffer solutions were changed and the pH was measured to ensure the adequate pH level.

Gamma-sterilized type 1 SR-PLLA screw bodies were cut to 12 mm long pieces before *in vitro*. Those together with a shorter left-over piece were immersed in a phosphate buffer solution (PBS, pH 7.4 ± 0.2) and held at 37 °C for periods of 1, 6, 9, 12, 15, 18, 21, 24 weeks. Each incubation set consisted of six samples (three compression tests per incubation period) and the samples for each incubation period were all placed in the same container. The samples were incubated in buffer solution, solution to mass ratio being ~100 ml g^{-1}. Every 3 weeks the buffer solutions were changed and the pH checked.

2.4. Weight measurements of cylindrical implants

All the cylindrical implants were weighed (accuracy of 0.1 mg) before and after the incubation period to calculate the water absorption to the composite structure. Before weighing the wet surface was quickly dried with a tissue paper to remove excess water from the surface of the implant. The weight change was calculated as % against the original sample weight and the actual weight change % was the average of three samples.

2.5. Thermal characterisation

The small left-over piece (screws type 1) was used for DSC (Differential Scanning Calorimetry) and GPC (Gel Permeation Chromatography) studies.

The DSC samples (6 ± 0.2 mg per sample) were heated from 30 to 250 °C at a rate of 20 °C min^{-1} and

after rapid cooling the samples were re-heated from 30 to 250 °C, at a rate of 20 °C min^{-1}. The melting temperature (T_m) was determined from the melting peak of the second heating and the melting enthalpy of the peak was determined. The equipment used was Perkin Elmer DSC7 (Perkin Elmer, Norwalk, CT, USA). The crystallinity was determined from the melting enthalpy using 93.7 J g^{-1} as the melting endotherm of 100% PLLA [15]. Thermal characterisation studies were not done for the cylindrical implants, because the constituents could not be extracted safely.

2.6. Molecular weight measurements

From the GPC (GPC, Waters, Milford, MA, USA) measurements the weight average molecular weight (M_w) and intrinsic viscosity (i.v.) were calculated with narrow polystyrene standards. Chloroform was used as a solvent and eluent. The equipment consisted of differential refractometer detector (Waters 410 RI) and HPLC-pump (Waters 515). The concentration of the sample was 0.1 mass%, injection volume was 150 μl, and the flow rate was 1 ml min^{-1}. Two high-resolution columns together with a guard column (PL-gel 5 μm mixed-C and PL-gel Guard) were used. Temperatures of the columns and the detector were 35 and 40 °C. Two repeat injections per sample were made and the data is the means of those two. Molecular weight measurements were not done for the cylindrical implants, because the constituents could not be extracted safely.

2.7. SEM (Scanning Electron Microscopy) studies

The scanning electron microscope Jeol T 100 (Jeol Ltd. Tokyo, Japan) was used to study the micro-scale changes in the surface of the cylindrical implants during the *in vitro*. The samples were gold sputtered before analysis.

3. Results and discussion

3.1. Composition of the cylindrical implants

The weight% ratios of the components in the composite implants were calculated and are presented in Table II. With this implant production method the obtained bioactive glass content in the *in vitro* samples was from 19 to 35 wt%. Large variation in the glass content is due to the production method where the matrix paste is hand-pasted to the knit. Previous results show that increasing the bioactive glass content in the composite increases the bioactivity [16], and thus the highest possible glass content was the goal.

3.2. Structural changes of the cylindrical implants and screws during hydrolysis

The Polyactive+BG rods started to crack after 1 week *in vitro* due to swelling of the rods causing the pressure against the shell and biodegradation. Because the implants were immersed in PBS free of compression pressure, the Polyactive + BG rods swelled and some expanded 1–3 mm vertically either up or down. This exposed the heads so that between 1 and 6 weeks the heads that were above the implant plane were cut off. At 15 weeks the shell layer of the implant was still firmly rolled around the Polyactive + BG core and no loosening or detachment of that material was noticed. When implanted, the core rods would stay between the adjacent vertebrae and expanding would actually improve the position. Swelling and fragmentation of the Polyactive + BG and the gaps between the glass particles and Polyactive *in vitro* was also noticed in [17].

The screws showed no structural changes during the hydrolysis.

TABLE II Weight contents of the components in the cylindrical implants

	Bioactive glass 13-93 (wt%)	Polyactive 70/30 (wt%)	P(L/D)LA 96/4 (wt%)	P(L/DL)LA 70/30 (wt%)
In vitro set	27.0 ± 8.4	10.8 ± 1.9	58.0 ± 8.1	4.2 ± 1.6
Set 1			99.8 ± 0.0	0.1 ± 0.0
Set 2			88.7 ± 2.1	11.3 ± 2.1
Set 3	20.8 ± 1.2		75.5 ± 1.5	3.7 ± 0.2
Set 4		14.2 ± 0.8	85.3 ± 0.7	0.4 ± 0.1
Set 5		13.7 ± 0.2	77.7 ± 1.8	8.6 ± 2.0
Set 6	23.7 ± 1.5	9.5 ± 0.2	62.6 ± 1.6	4.2 ± 0.3
Set 7	3.6 ± 0.0	12.3 ± 0.1	83.4 ± 0.0	0.6 ± 0.1
Set 8	3.4 ± 0.1	11.3 ± 0.3	76.6 ± 0.1	8.7 ± 0.3
Set 9	23.2 ± 3.8	9.4 ± 1.0	63.7 ± 3.5	3.6 ± 0.7

In vitro set ($n = 15$); Set 1–9 ($n = 3$).

3.3. Weight change of the cylindrical implants

The implants gained weight approximately 5 wt% after 1 h in de-ionised water. After 1 week *in vitro* the implants weight had increased roughly 20 wt% and it remained at the same level until 15 weeks *in vitro*. The weight increase of ~5% in 1 h is due to the water absorption of the Polyactive + BG rods [17], after 1 h the weight gain is due to the swelling of the Polyactive + BG rods and water absorption into the matrix through the pores that are on the surface of the implant. The fragmented Polyactive + BG debris from 1 to 6 weeks were weighed as well and thus did not affect the weight measurements of the implant.

3.4. SEM analysis of the cylindrical implants

The images in Fig. 2 show the changes in cylindrical implant surface during 12 weeks in hydrolysis. In Fig. 2(A) and (C) the bioactive glass particles are clearly visible. There are no visible structural changes after 12 weeks in the surface topography. By comparing the high magnifications Fig. 2(B) and (D), it is noticed that after 12 weeks the surface is covered with white agglomerates presumably calcium phosphate particles. Calcium phosphate deposition with bioactive glass type 13–93 in PBS solution on the surface of poly(L/DL)lactide 70/30 has been noted and studied [18, 19].

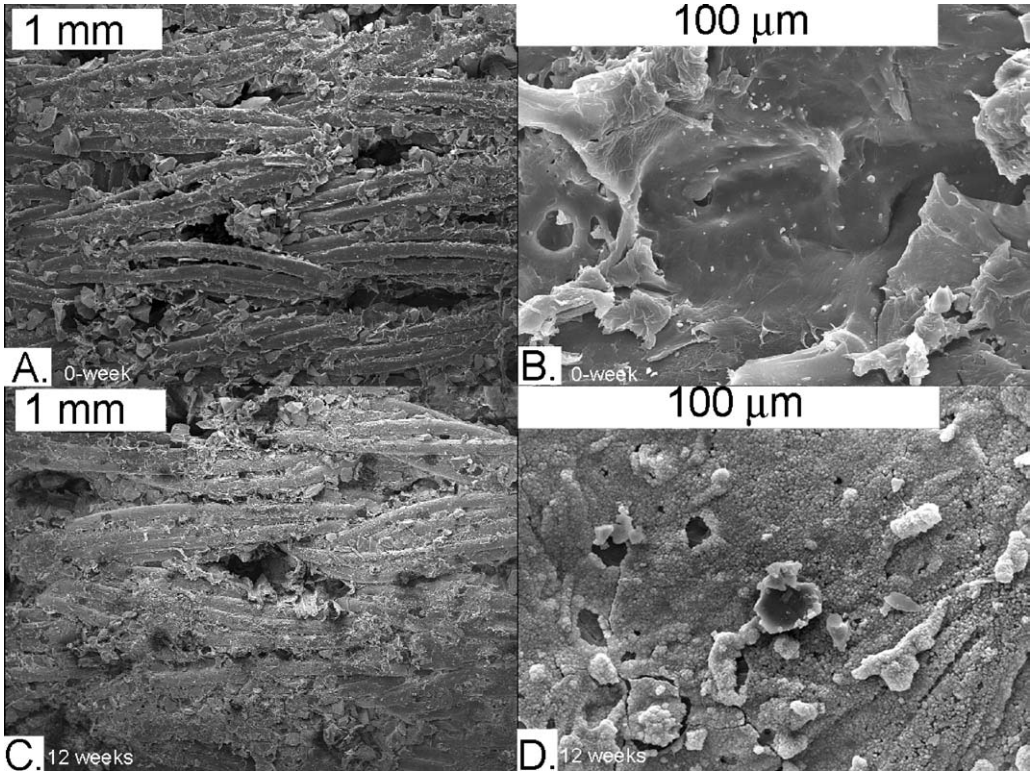

Figure 2 Scanning electron microscopy images from cylindrical implant surface, (A) 35× (B) 1000× magnification 0-week in vitro and (C) 35× (D) 1000 × magnification 12 weeks *in vitro*.

3.5. Mechanical properties

3.5.1. Initial mechanical properties of the cylindrical implants

The reference series (Tables I and II) were mechanically tested and the results are shown in Fig. 3. The influence of the core material and reinforcement matrix was studied in the reference series.

The influence of the core: The core (sets 4 & 7) had a 26–30% increase in modulus with both core types and 14% increase in stiffness with Polyactive + BG core, when compared to the implant without the core (set 1). The Polyactive core (set 5) had an 18% and Polyactive + BG core (set 8) had a 10% increase in modulus when compared to the implant with reinforcement matrix polymer and no core (set 2). The core had no significant change in stiffness values while the reinforcement polymer was filled (sets 3, 6 & 9) or unfilled (sets 2, 5 & 8) with BG. When reinforcement polymer with BG filler was used there was a 19% increase with Polyactive core (set 6) and 10% increase with Polyactive + BG core (set 9) compared to the samples without the core. The slightly higher modulus values with Polyactive core compared to the Polyactive + BG core could be due to the BG particles in Polyactive, BG filler in the Polyactive rod allows the crack development with lower loads and acts as a crack initiators in the Polyactive rods. The lower modulus of the Polyactive rods with bioactive glass filler was also noticed earlier [17].

The influence of reinforcement matrix: The reinforcement matrix polymer increases both stiffness and the modulus of the samples. When the BG filler is added to the reinforcement polymer the stiffness and modulus increases yet again. This trend is clearly seen in Fig. 3. From the sets 1–9 the set 9 was chosen for the *in vitro* studies because it had best strength and modulus combination, when compared to other sets, and it had the highest BG content to improve osteoconductivity.

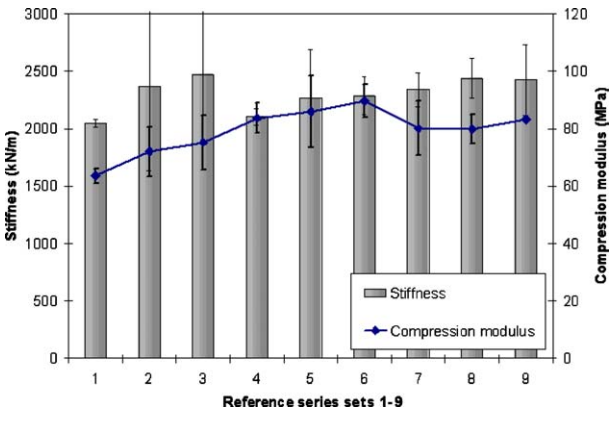

Figure 3 Compression modulus and stiffness of the cylindrical implants.

3.5.2. Mechanical properties of the cylindrical implants in vitro

No significant changes in mechanical properties were noticed during the 15-week hydrolysis (Fig. 4). The modulus of the hydrolysis samples stayed between the error margins through out the hydrolysis and the modulus was 100 ± 10 MPa with stiffness of 3400 ± 250 kN m^{-1} at 15 weeks *in vitro.* Typical stress—compressive strain curve (Fig. 5) shows that the 15-week hydrolysis samples have the highest stress (30 MPa) and lowest compressive strain (0.3 mm mm^{-1}) values. The compression of cylindrical implants in the regions 0–2, 2–4

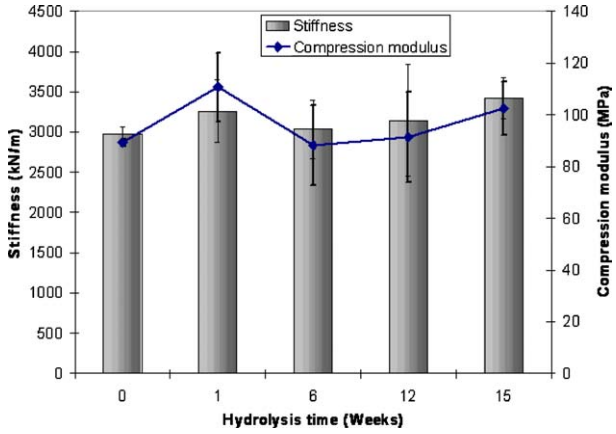

Figure 4 In vitro behavior of the cylindrical implant.

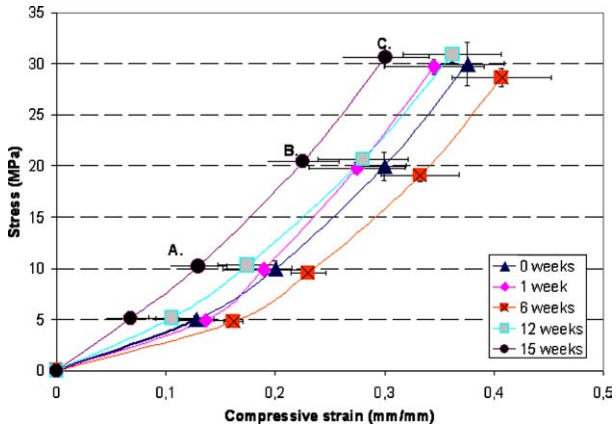

Figure 5 Stress-compressive strain curve of the cylindrical implants (A) 2 kN, (B) 4 kN, and (C) 6 kN.

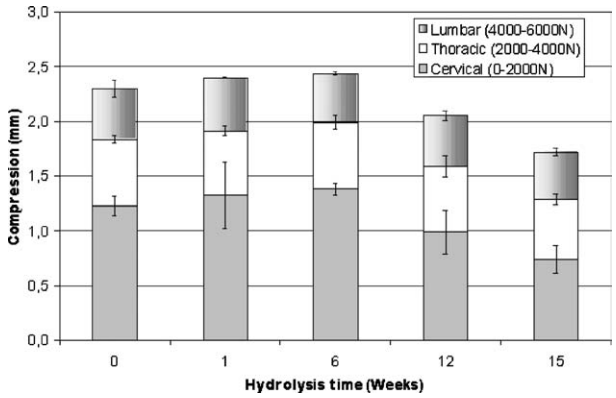

Figure 6 Compression of the cylindrical implants in compression.

and 4–6 kN are in Fig. 6. The compression of the cylindrical implant was 0.7 ± 0.1 mm at 2 kN and 1.3 ± 0.2 mm at 4 kN with 15-week samples. The highest compression properties were noticed with the 15-week samples and this is mainly due to the absence of Polyactive + BG rod ends reaching above the plain of the implant. The Polyactive + BG above plain compression is part of the 0 to 2 kN compression and this has changed with the 12 and 15-week samples, whereas the compression distance from 2 to 6 kN remains the same throughout the hydrolysis.

The average 100 MPa modulus would be adequate modulus for lumbar, thoracic and cervical regions for the canine spine model of the spine, the current stress 30 MPa at compressive strain 0.3 mm mm^{-1} is 50% higher than with the composite semi- IPNs [20]. Each human cervical vertebra stands ∼2 kN, thoracic 2–4 kN and lumbar 4.5–8.3 kN force before breaking [21], and no breakage was observed with cylindrical implants in any of the compressions. Compression tests performed for cadaver region Th_{11}-L_3 samples (4 intervertebral discs present) compression shortening in 2 kN was from 3 to 5.8 mm, in 4 kN from 4.8 to 7.7 mm and in 6 kN from 6.5 to 8.3 mm (some samples already failed at before 6 kN) [22]. The compression of the cylindrical implants in those regions can be seen in Fig. 6 and compared these to the shortening of the sample with four intervertebral discs [22] we see that the cylindrical implant shortening in 0–2 kN and 2–4 kN is comparable to human intervertebral disc behaviour. The cylindrical implants showed higher stiffness when compared to the TFM (titanium fiber mesh) implants and tricortical bone grafts studied by Hoshijima *et al*. [6] and to canine composite disc spacers studied by Vuono-Hawkins *et al.* [23].

3.5.3. Mechanical results of the screws

The compression modulus of the solid screws was three times greater than those of the cannulated screws or the cannulated screws with rod inserted inside of cannula. The cannulated screws failed at forces below 400 N and had compression strength at yield between 7.3–7.6 MPa. The cannulated screws with rods inserted into the cannula had maximum break force of 420 N and compression strength at yield point 8.1–8.8 MPa. These two screw types used this way were not strong enough for the canine spine intervertebral disc purposes. Although the modulus values would have been adequate the compression strength was not sufficient [20]. During the 24-week hydrolysis no critical changes in the modulus were noticed (Fig. 7). The solid screws had modulus of 390 ± 30 MPa after 24-week hydrolysis. This modulus is sufficient for canine spine for cervical, thoracic and lumbar regions [20]. The increase in compression distance of the 4 to 6 kN region can be seen from the Fig. 8. The compression distance values when compared to human spine [22] were sufficient for the cervical spine 0 to 2 kN but slightly low for human thoracic and lumbar area purposes. From the curves it was noted that all the screws in the hydrolysis series had their yield point after 0.61 mm compression. The

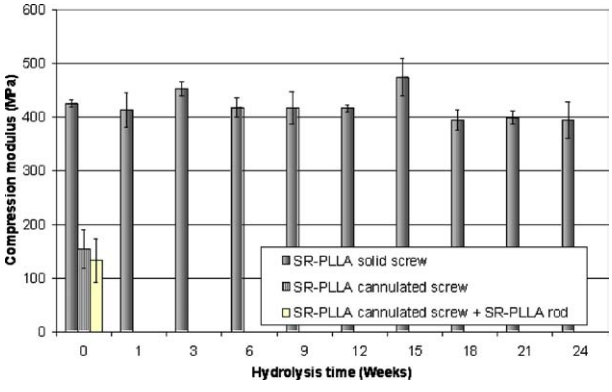

Figure 7 Compression modulus of the screws in hydrolysis.

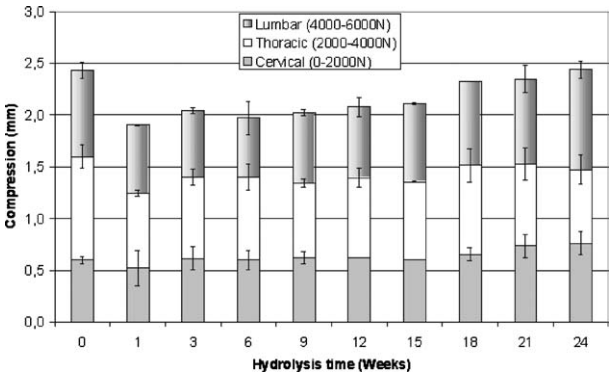

Figure 8 Compression of the screws in hydrolysis.

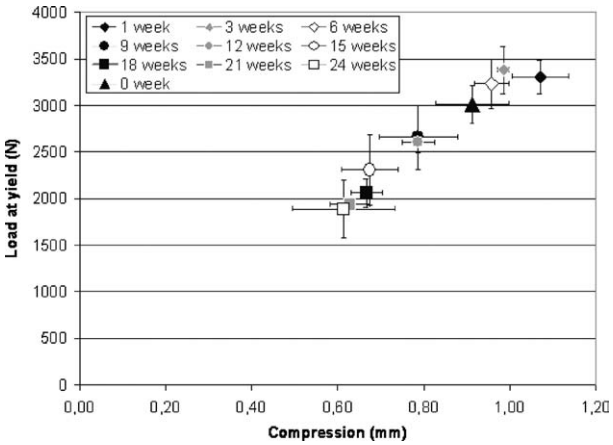

Figure 9 Yield point of the threads in hydrolysis.

yield point decrease due to the softening and failure of the screw threads can be seen during the hydrolysis (Fig. 9). If the implantation to the spine is done so that the threads are embedded in bone, the dynamics of the screws changes and there would not be a visible yield point of the threads. Now this yield point exists in this data due to the compression between the steel plates and is a good indicator of minor degradation behaviour.

3.6. Molecular weight analysis of the screws

The weight average molecular weight (M_w) and the intrinsic viscosity (i.v.) data from the 24-week hydrolysis is in Table III. The M_w of the screws decreased by 45% and the i.v. by 37% during the hydrolysis. Pohjonen *et al*. studied the SR-PLLA Ø 4.5 mm screws and they noticed 43% decrease in viscosity average molecular weight (M_v) after 15-week hydrolysis which corresponds with the results of this study [24].

TABLE III Molecular weight and crystallinity of the solid SR-PLLA screws

In vitro weeks	M_w (g mol^{-1})	i.v. (dl g^{-1})	*In vitro* weeks	T_m (°C)	Crystallinity (%)
0	56400	1.47	0	177	55
1	57000	1.48	1	176	56
3	59100	1.53	3	176	57
6	50100	1.34	6	176	58
9	46800	1.27	9	176	61
12	43600	1.21	12	176	62
15	39700	1.13	15	176	67
18	40500	1.33	18	176	64
21	39500	1.28	21	178	57
24	30700	0.93	24	176	62

M_w = Weight average molecular weight ($n = 2$).
i.v. = Intrinsic viscosity ($n = 2$).

3.7. Thermal properties of the screws

The crystallinity of the SR-PLLA solid screws increased from 55 to 62% in 24-week hydrolysis. Reported increase from 63 to 70% in 15-weeks of hydrolysis [24] and 60 to 65% increase in crystallinity in 24 weeks *in vitro* [25] are slightly higher than the initial and post *in vitro* crystallinity of the studied screws. There was no dramatic change in T_m from 177 °C during 24 weeks *in vitro* which corresponds well with previous study [25].

4. Conclusions

In this study the screws and the cylindrical implant were planned as intervertebral disc replacement devices to ossify the adjacent vertebrae together. The screws and the cylindrical implants are both mechanically suitable for canine intervertebral studies and the cylindrical implant, with present design, also has good mechanical properties for human thoracic and cervical intervertebral disc replacement purposes. Degradation rate of the screws is sufficient but the strength in the transverse direction to the screw axis is not yet adequate for human intervertebral purposes.

The cylindrical implant is a new concept and some detailed design enhancements must be taken to ensure the perfect fit of the implant to the target site. This is relatively easy because the manufacturing procedure of the implant allows easy changes in design of different size intervertebral disc implants. The implant surface has a lot of bioactive glass, the surface topography is not polished and there is porosity on the surface, all this could lead to higher activity on the surface compared to smooth and polished surface without bioactive components. Because the cylindrical implants are reasonably stiff we do not expect the implant to fully recover (to return to its original height post testing). Therefore if these implants are used, the stresses in the operated area should not be high during the fusion period to avoid the permanent compression and the loosening of the implant. But if there should be higher stresses in the operated joint the implant remains unbroken.

Preliminary tests using cylindrical implants and screws on pigs have been performed (L3-L4 and L4-L5 lumbar discs were operated) and the results have shown ossification with both types of implants in 15-week follow up. Cylindrical implants showed better anatomical results compared to screws when the disc spaces were compared [26].

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