Strength Analysis of 6 Resorbable Implant Systems: Does Heating Affect the Stress-Strain Curve?

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Purpose: The objective was to directly compare the strength of 6 different resorbable implant plating systems using an in vitro model before and after heating.

Materials and Methods: Red oak wood was cut and fixated using various resorbable plates and screws. Vertical load was applied and the specimens fractured, while a test machine gathered data. This was repeated after heating of the specimens.

Results: Several parameters were analyzed, and force versus displacement curves were plotted for each specimen.

Conclusions: There were no statistically significant differences for total maximum loads between heat-treated and non heat-treated specimens. There were differences in strengths amongst the various systems.

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Over the past several years we have seen an evolution in the types of resorbable plating systems available. There has not been a reported study directly comparing the strength of these systems. This in vitro study compares the load-bearing properties of 6 commercially available resorbable plating systems in a fracture model. They were also tested to determine if preheating and bending the plates decreased their strength. Our results show that the immediate strength of the resorbable systems vary. One polymer configuration performed superiorly. This suggests that not all systems may be appropriate for the fixation of load-bearing fractures.

Resorbable plates and screws are composed of various combinations of poly (α-hydroxypolyesters). An attempt to obtain strength of resorbable plates and screws but also maintain convenient resorption rates has led various companies to modulate implant properties via changes in morphology, composition, molecular weight, crystalline/amorphous ratio, thermal history, polymer processing methods, distribution of forces, and sterilization technique of the product.[1-3] This in vitro study compares the load-bearing properties of 6 commercially available 2.0 to 2.1 mm resorbable plating systems in a fracture model. This comparison is made against the same set of plates and screws after heating per the manufacturers' instructions.

Materials and Methods

As in a previous study, red oak wood board was cut into 12 × 28 × 160 mm sections.[4] Care was taken to ensure uniformity in grain size, quality, and alignment of the wood sections or blocks. The wood blocks were

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Table 1. GROUP CONTENTS

Group	Characteristics
Inion	Single 10-hole Inion (Stryker Leibinger) resorbable plate, cut to 6 holes, with six 2.0 × 7 mm resorbable screws per plate
InionH	Single 10-hole Inion (Stryker Leibinger) resorbable plate (after heating), cut to 6 holes, with six 2.0 × 7 mm resorbable screws per plate
Lactosorb	Single 8-hole Lactosorb (Lorenz) resorbable plate, cut to 6 holes, with six 2.0 × 7 mm resorbable screws per plate
LactosorbH	Single 8-hole Lactosorb (Lorenz) resorbable plate (after heating), cut to 6 holes, with six 2.0 × 7 mm resorbable screws per plate
Macropore	Single 8-hole Macropore (Medtronic) resorbable plate, cut to 6 holes, with six 2.0 × 6 mm resorbable screws per plate
MacroporeH	Single 8-hole Macropore (Medtronic) resorbable plate (after heating), cut to 6 holes, with six 2.0 × 6 mm resorbable screws per plate
ResorbX	Single 8-hole Resorb-X (KLS Martin) resorbable plate, cut to 6 holes, with six 2.1 × 7 mm resorbable screws per plate
ResorbXH	Single 8-hole Resorb-X (KLS Martin) resorbable plate (after heating), cut to 6 holes, with six 2.1 × 7 mm resorbable screws per plate
Synthes	Single 8-hole Synthes (Synthes) resorbable plate, cut to 6 holes, with six 2.0 × 6 mm resorbable screws per plate
SynthesH	Single 8-hole Synthes (Synthes) resorbable plate (after heating), cut to 6 holes, with six 2.0 × 6 mm resorbable screws per plate
Synthes Rapid	Single 8-hole Rapid (Synthes) resorbable plate, cut to 6 holes, with six 2.0 × 6 mm resorbable screws per plate
Synthes RapidH	Single 8-hole Rapid (Synthes) resorbable plate (after heating), cut to 6 holes, with six 2.0 × 6 mm resorbable screws per plate

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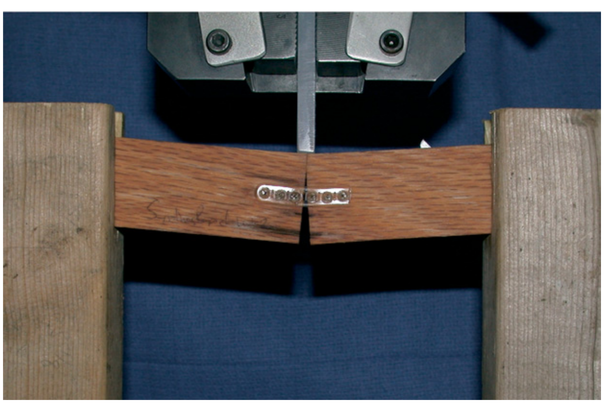

FIGURE 1. Vertical load testing.

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Table 2. MAXIMUM LOAD (MEAN VALUES ± STANDARD DEVIATIONS, KG)

Resorbable Plate	No Heat Treatment	Heat Treated	Significance of Difference*
Inion 2.0	8.45 ± 1.81	10.08 ± 2.15	nS
Lactosorb	8.51 ± 1313	7.00 ± 2.10	nS
Macropore	5.55 ± 1.69	6.01 ± 2.25	nS
ResorbX	2.94 ± 0.40	2.37 ± 0.37	nS
Synthes	4.27 ± 0.76	4.87 ± 0.82	nS
Synthes Rapid	8.65 ± 1.51	7.24 ± 2.25	nS

*nS, $P > .05$; pS, $P < .05$; S, $P < .01$.

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Table 3. DISPLACEMENT AT MAXIMUM LOAD (MEAN VALUES ± STANDARD DEVIATIONS, MM)

Resorbable Plate	No Heat Treatment	Heat Treated	Significance of Difference*
Inion 2.0	13.37 ± 3.12	16.56 ± 2.45	nS
Lactosorb	4.99 ± 0.95	6.53 ± 3.58	nS
Macropore	5.55 ± 1.69	4.37 ± 1.75	nS
ResorbX	2.52 ± 0.73	2.72 ± 0.47	nS
Synthes	4.40 ± 0.58	5.57 ± 0.63	S
Synthes Rapid	7.26 ± 0.95	5.44 ± 1.63	pS

*nS, $P > .05$; pS, $P < .05$; S, $P < .01$.

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then cut in half with a reciprocating saw. The plates were cut to 6 holes using a heated plate cutter, and then placed into 1 of 12 groups (Table 1). Half the groups were placed into water baths set at the recommended temperatures per the manufacturer. They were then "worked" by placing and removing a 90° twist. The plates were then adapted to the wooden blocks, 3 holes per each side of the simulated fracture, and secured with 6 resorbable screws. The screw lengths ranged from 6 to 7 mm, according to the plating system. All groups were then soaked in 37°C, 0.9% saline solution for 24 hours to simulate an in vivo environment before testing. A jig was designed to passively support the wood blocks at each end. There were 12 experimental groups with 6 identical specimens in each group (out-

Table 4. APPLIED LOAD AT 1 MM AND 2 MM DISPLACEMENT

Resorbable Plate	1 mm Displacement		2 mm Displacement	
	No Heat Treatment	Heat Treated	No Heat Treatment	Heat Treated
Inion 2.0	1.36 ± 0.82 (60.09%)	0.82 ± 0.23 (28.66%)	2.55 ± 1.27 (49.69%)	1.60 ± 0.48 (29.92%)
Lactosorb	1.98 ± 0.59 (29.99%)	1.39 ± 0.23 (16.46%)	3.81 ± 1.15 (30.13%)	4.73 ± 0.53 (11.21%)
Macropore	1.39 ± 0.23 (16.46%)	1.37 ± 0.34 (24.91%)	2.24 ± 0.40 (15.70%)	2.91 ± 0.60 (20.73)
ResorbX	1.54 ± 0.61 (39.31%)	1.20 ± 0.20 (16.68%)	2.13 ± 0.57 (26.74%)	1.97 ± 0.35 (17.84%)
Synthes	1.34 ± 0.24 (17.80%)	1.42 ± 0.16 (11.26%)	2.45 ± 0.37 (14.93%)	2.50 ± 0.32 (12.81%)
Synthes Rapid	1.48 ± 0.18 (11.97%)	1.59 ± 0.22 (14.11%)	3.07 ± 0.35 (11.34%)	3.29 ± 0.63 (19.05%)

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lined in Table 1). All mechanical testing was performed on a Satek T5000 (Instron, Grove City, PA) universal testing machine. The specimens were individually tested with a vertical load applied over the fracture site at a crosshead speed of 0.5 mm/min with the fixated blocks statically supported at their ends in the jig (Fig 1).

Results

The test machine recorded the force versus displacement behavior automatically for each specimen (n = 72). For each specimen, the slope of the initial force versus displacement curve, representing the stiffness of the fixation system, was calculated (kgf/mm). The peak load in kilogram force (kgf) was also recorded. The maximum load each plate was able to sustain was recorded before and after heat treatment (Table 2). The amount of plate displacement ("bending") at this maximum load was also recorded (Table 3). The amount of load at displacements of 1 mm and 2 mm was identified and plotted (Table 4; Figs 2, 3). The experimental data were subjected to a one-way ANOVA. Differences between the data were identified by means of a post-hoc Scheffé multiple comparison test at an a priori $\alpha = 0.05$ using the Prostat statistics package (Poly Software International, Pearl River, NY). Statistical analysis is reported in Tables 5 through 8.

Discussion

The 6 groups were chosen for this study because of their popularity and similarity of use. However, there are several important differences regarding their characteristics. The Inion system (Stryker Leibinger, Oklahoma City, OK) is composed of polylactic acid in its L-isomer form (PLLA), polyglycolic acid (PGA), poly D, L-lactide acid (PDLLA), and TMC (trimethylene carbonate). The resorption time is 1 to 3 years. The Lactosorb system (Lorenz, Jacksonville, FL) was the first on the market and is composed of 82% PLLA and 18% PGA. The resorption time is less than 1 year. Resorb X (KLS Martin, Jacksonville, FL) is composed of pure PDLLA. It is completely amorphous and retains its mechanical properties over a period of approximately 10 weeks before beginning the resorption process. The resorption time is 1 year.[5] Synthes (Synthes, West Chester, PA) is composed of 70% PLLA and 30% PDLLA. Its resorption time is 2 years. Synthes Rapid (Synthes) is manufactured from 85:15 poly (L-lactide-co-glycolide). The resorption time is 12 months. The BioResorbable Fixation System (Osteomed, Addison, TX) has the same chemical composition as the Synthes product and therefore was not individually studied. All resorption data previously mentioned was gathered from the manufacturers. A review of degradation versus resorption rates of all plating systems

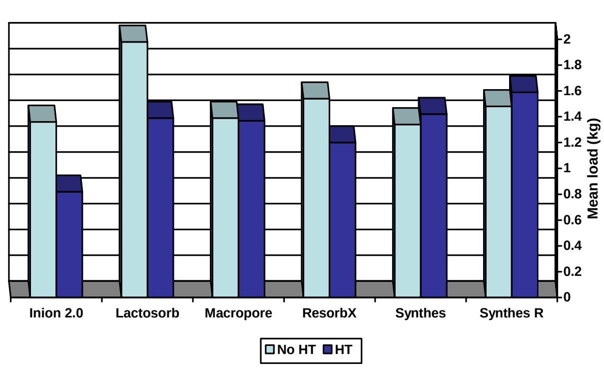

FIGURE 2. Applied load required for 1 mm displacement.

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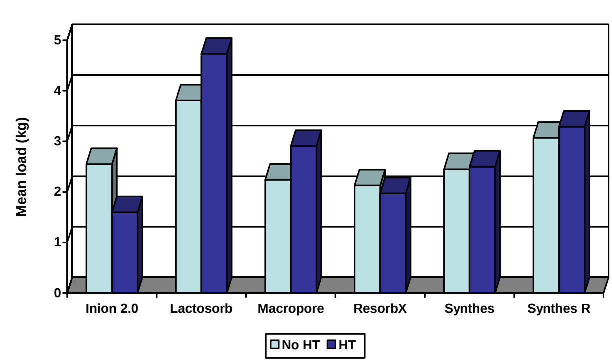

FIGURE 3. Applied load required for 2 mm displacement.

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Table 5. STATISTICAL ANALYSIS: LOAD REQUIRED FOR 1 MM DISPLACEMENT: NON HEAT-TREATED

	Inion 2.0	Lactosorb	Macropore	ResorbX	Synthes	Synthes Rapid
Inion 2.0	—					
Lactosorb	pS	—				
Macropore	Ns	pS	—			
ResorbX	Ns	Ns	Ns	—		
Synthes	Ns	pS	Ns	Ns	—	
Synthes Rapid	Ns	Ns	Ns	Ns	Ns	—

Ns, $P > .05$; pS, $P < .05$; S, $P < .01$; hS, $P < .001$.

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Table 6. STATISTICAL ANALYSIS: LOAD REQUIRED FOR 1 MM DISPLACEMENT: HEAT-TREATED

	Inion 2.0	Lactosorb	Macropore	ResorbX	Synthes	Synthes Rapid
Inion 2.0	—					
Lactosorb	**hS**	—				
Macropore	Ns	Ns	—			
ResorbX	Ns	**S**	Ns	—		
Synthes	Ns	Ns	Ns	Ns	—	
Synthes Rapid	**S**	Ns	Ns	Ns	Ns	—

Ns, $P > .05$; pS, $P < .05$; S, $P < .01$; hS, $P < .001$.
Note: The significant and highly significant values are in **bold** type.

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Table 7. STATISTICAL ANALYSIS: LOAD REQUIRED FOR 2 MM DISPLACEMENT: NON HEAT-TREATED

	Inion 2.0	Lactosorb	Macropore	ResorbX	Synthes	Synthes Rapid
Inion 2.0	—					
Lactosorb	**hS**	—				
Macropore	Ns	**hS**	—			
ResorbX	Ns	**hS**	Ns	—		
Synthes	Ns	**hS**	Ns	Ns	—	
Synthes Rapid	Ns	**hS**	Ns	Ns	Ns	—

Ns, $P > .05$; pS, $P < .05$; Sm, $P < .01$; hS, $P < .001$.
Note: The significant and highly significant values are in **bold** type.

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Table 8. STATISTICAL ANALYSIS: LOAD REQUIRED FOR 2 MM DISPLACEMENT: HEAT-TREATED PLATES

	Inion 2.0	Lactosorb	Macropore	ResorbX	Synthes	Synthes Rapid
Inion 2.0	—					
Lactosorb	**hS**	—				
Macropore	Ns	Ns	—			
ResorbX	Ns	Ns	Ns	—		
Synthes	Ns	**hS**	Ns	Ns	—	
Synthes Rapid	Ns	Ns	Ns	Ns	Ns	—

Ns, $P > .05$; pS, $P < .05$; S, $P < .01$; hS, $P < .001$.
Note: The significant and highly significant values are in **bold** type.

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published in peer-reviewed journals as of early 2004 demonstrated that degradation occurs between 9 and 18 months after placement in Lactosorb (Lorenz) and 8 and 13 months in DeltaSystem (Leibinger).[6]

The purpose of this in vitro study was to determine if there was a statistical significance in strength between heat-treated and non heat-treated plates and screws, as well as to compare 6 products. A previous study inconclusively suggested that heat-treating resorbable plates may decrease their strength properties.[7] No statistically significant differences for total maximum loads between heat-treated and non heat-treated specimens were found (Table 2). Heat-treating, however, did have a statistically significant effect on the displacement at maximum load of the Synthes plates ($P < .01$) and the Synthes Rapid plates ($P < .05$) (Table 3). No statistically significant difference ($P > .05$) was found between the loads at 1 and 2 mm displacement for any of the heat-treated and non heat-treated specimens (Tables 4-8; Figs 2, 3). The Lactosorb group performed the best with regard to the force required to cause a clinically significant displacement of 1 to 2 mm (Figs 2, 3). This achieved statistical significance in both the 1 and 2 mm groups and was uniformly superior at 2 mm displacement. The Resorb X group performed the worst with regard to maximum load as well as displacement at maximum load (Tables 2, 3).

Our results show that the immediate strength of resorbable systems varies. When the systems were first introduced their compositions tended toward "stronger" implants and were used in many clinical scenarios. With time, the resorbable products have become more popular in the pediatric population. Manufacturing companies have responded by creating "faster resorbing" products. There is a delicate balance between strength and resorption rates, and anecdotally many have voiced concerns about the trade-off of strength for faster resorption. As with all new products, the prudent surgeon will take into consideration the clinical scenario as well as the available literature when choosing to use these systems.

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