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LOWER EXTREMITY REVIEW

February 17 / volume 14 / number 2

3D PRINTING OF FOOT ORTHOSES:

*Clinical feasibility and
cost-benefit analyses*

PLUS:

OSTEOARTHRITIS

DOES HISTORY OF RUNNING
PROTECT AGAINST KNEE OA?

O&P

MANAGEMENT OF PATIENTS
WHO ARE HARD ON DEVICES

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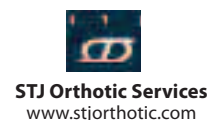
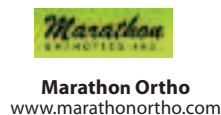
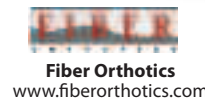
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February 2017

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3D PRINTING OF FOOT ORTHOSES:

CLINICAL FEASIBILITY AND COST-BENEFIT ANALYSES

Several technical issues currently limit the cost effectiveness of 3D printing custom foot orthoses, but these will likely be addressed in the near future with the emergence of larger and faster 3D printers.

By Steven Hoeffner, PhD; Timothy Pruett; Breanne Przeustrzelski, MS; Brian Kaluf, CP; Nikki Hooks, CO; Katelyn Ragland; Shannon Hall; Kyle Walker; Dan Ballard, CPed; and John DesJardins, PhD

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Her head's in the game

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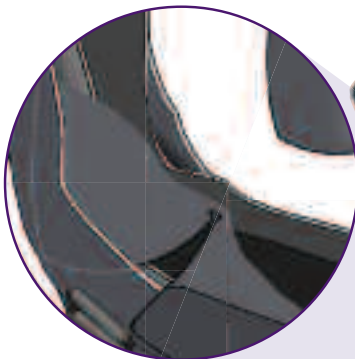
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It's more difficult to assess the effects of head impacts in female lacrosse players than in their male counterparts. But it's no less important, particularly with regard to lower extremity injury prevention.

Head impacts in male lacrosse players can be quantified with the use of

instrumented helmets, as Sacred Heart University researchers did in a recent study examining associations between subconcussive impacts and balance (see "Subconcussive subtleties: Lacrosse study links balance, impacts," page 13).

Female lacrosse players typically don't wear helmets, which have been deemed unnecessary since the rules of the women's game prohibit contact between players. And yet, despite the official emphasis on noncontact play for women, multiple studies have found that concussion risk is similar for both genders, at both the high school and college levels. And, in a 2014 University of Virginia study in which head impacts were assessed using mastoid-patch accelerometers, the number of head impacts was similar for men's and women's college lacrosse players.

That's why, although the Sacred Heart study included only male players, its findings are likely relevant for female players as well. The study found higher levels of subconcussive impacts accumulated during the course of a lacrosse season were associated with greater deterioration in scores on the foam-surface aspects of the Balance Error Scoring System test between the pre- and postseason.

It's unclear whether the subconcussive impacts directly caused the balance deficits, but that certainly makes intuitive sense, since postconcussion balance impairment is common and can persist long after most concussion symptoms have resolved (see "Concussion repercussions: Studies explore lower extremity effects," June 2016, page 13).

out on a limb: Her head's in the game

Although researchers are only beginning to explore the injury implications of subconcussive impacts, multiple studies have suggested impaired balance alone can increase the risk of lower extremity injury in athletes—including ankle sprains and anterior cruciate ligament injuries, which account for up to 30% of injuries in female lacrosse players.

And there's at least some evidence to suggest the relationship between balance and lower extremity injury may be more pronounced in female athletes than in male athletes. In a 2006 study of high school basketball players, a composite reach distance of less than 94% of limb length on the Star Excursion Balance Test performance was associated with a 6.5 times greater risk of lower extremity injury in girls—but no similar association was seen in boys.

Studies of head impacts in male lacrosse players also have lower extremity injury implications for their female counterparts.

It seems clear that if lower extremity practitioners who work with female lacrosse players aren't monitoring those athletes' balance during the course of a season and implementing balance training protocols as needed, they should be.

But it also seems that efforts to reduce subconcussive head impacts in female lacrosse players could help reduce lower extremity injury rates even further. That starts with better enforcement of those rules stipulating noncontact play in the women's game. Because the helmets worn by male lacrosse players do facilitate the study of head impacts, but no helmet has yet been proven to neutralize the effects of those head impacts in athletes of either gender.

Jordana Bieze Foster, *Editor*

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Subconcussive subtleties Lacrosse study links balance, impacts

By Katie Bell

Measures of cumulative subconcussive head impacts during a men's lacrosse season are associated with decreases in balance scores from pre- to postseason, according to findings from Sacred Heart University in Fairfield, CT, that could have implications for lower extremity injury risk.

The findings suggest that, even in the absence of a concussion, repetitive subconcussive impacts can negatively affect an athlete's balance, which in turn can increase the risk of lower extremity injury, said Theresa L. Miyashita, PhD, ATC, assistant professor in the Athletic Training Education Program at Sacred Heart University and first author of the study.

"Balance deficits are linked to a predisposition for lower extremity injuries," Miyashita said.

For example, a 2006 study of high school basketball players found that poorer preseason performance on the Star Excursion


Stiffer shoes improve running energetics as long as first MTP flexion is preserved

Increasing running shoe bending stiffness helps improve running energetics up to the point at which it impairs metatarsophalangeal (MTP) joint flexion—a threshold that varies between individuals—according to research from the Republic of Korea.

Investigators from the Korea Advanced Institute of Science and Technology in Daejeon analyzed 19 individuals as they ran while wearing lightweight running shoes fitted with carbon-plate insoles of five different bending stiffnesses.

They found that increasing bending stiffness assisted with propulsion during running, reducing the metabolic cost of running by about 1%. However, at a certain level, the increased

elasticity began to interfere with the natural flexion of the first MTP joint, reducing the contribution of ankle joint torque to push-off and counteracting the metabolic benefits. Within the study population, the threshold of bending stiffness for optimal energetics varied significantly from one runner to the next, suggesting running shoe design may need to be tuned to an individual runner's needs.

The findings were published in January by the *Journal of Biomechanics*. 

—Jordana Bieze Foster

Source:

Oh K, Park S. The bending stiffness of shoes is beneficial to running energetics if it does not disturb the natural MTP joint flexion. *J Biomech* 2016 Jan 18. [Epub ahead of print]



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Balance Test was associated with a higher risk of lower extremity injury during the season.

The Sacred Heart study, which was epublished by *Sports Health* in January, included 34 collegiate men's lacrosse players (average age 19 years) who wore instrumented helmets that collected head impact exposure data. The researchers evaluated linear acceleration along with two injury tolerance scores, head injury criteria and Gadd Severity Index.

Continued on page 14


Long after return to play, ACL injury takes toll on perceived knee function

Perceived knee function is poorer in athletes who successfully return to play after an anterior cruciate ligament (ACL) injury than in their uninjured counterparts, despite no strength or balance differences between the groups, according to research from Norway.

Investigators from the Oslo Sports Trauma Research Center analyzed 858 elite handball and soccer players; 80 had sustained an ACL injury one to six years previously (mean 3.5 ± 2.5 years).

Quadriceps and hamstrings strength and dynamic balance did not differ significantly between ACL-injured legs and uninjured legs for the 858 athletes overall. However, quadriceps and hamstring strength were

significantly lower and knee laxity was significantly greater for the ACL-injured limbs than the contralateral limbs of the same players. Those asymmetries may help explain why perceived knee function, based on the Knee Injury and Osteoarthritis Outcome Score (KOOS), was significantly lower for ACL-injured knees than for the knees of uninjured players.

The findings were epublished in January by the *Scandinavian Journal of Medicine & Science in Sport*. 

—Jordana Bieze Foster

Source:

Myklebust G, Bahr R, Nilstad A, Steffen K. Knee function among elite handball and football players 1 to 6 years after anterior cruciate ligament injury. *Scand J Med Sci Sport* 2017 Jan 20. [Epub ahead of print]

in the moment: sports medicine

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The participants also completed a Balance Error Scoring System (BESS) test once during the preseason and once during the postseason.

The number of errors on the BESS test increased from pre-season to postseason for double-leg stance on foam, tandem stance on foam, total number of errors on a firm surface, and total number of errors on foam. The total errors on the foam were significantly correlated with linear acceleration, head injury criteria, and Gadd Severity Index scores.

Miyashita said the researchers believe the association found between the subconcussive measures and BESS scores on the foam surface suggests the cumulative subconcussive impacts contributed to the decrease in BESS performance from pre- to postseason.

Correlations between subconcussive impacts and change

in BESS score were significant for the foam-based BESS trials, but not the trials done on a firm surface; this suggests assessments that highly stress the vestibular system may be needed to detect microtrauma to that system caused by repetitive subconcussive impacts, Miyashita said.

The findings also suggest the BESS test, which is often included in concussion management protocols, could also be used to help screen for high levels of subconcussive impacts.

Douglas Martini, PhD, postdoctoral researcher at the Sensorimotor Neuroimaging Laboratory at Oregon Health & Science University in Portland, noted that, compared with sideline concussion evaluation tests, "the BESS is easier and cheaper to implement, which is important for schools with limited discretionary funds."


A growing body of research

suggests athletes who suffer concussions are more likely than other athletes to sustain a lower extremity injury (see "Concussion repercussions: Studies explore lower extremity effects," June 2016, page 13), but it remains to be seen whether similar injury risks are associated with subconcussive impacts.

"I'm hesitant to say that cumulative subconcussive impacts would increase the likelihood of sustaining a musculoskeletal injury," Martini said. "However, I don't think it's unrealistic to expect the combination of subconcussive impacts and a concussion history (particularly three or more previous concussions) to have a meaningful impact on the odds of sustaining a musculoskeletal injury."

Also yet to be determined is whether head impacts are a cause or an effect of balance

impairment, Martini noted.

"The 'chicken or the egg' dilemma has yet to be answered for concussions," he said. "That is, do some athletes have poorer balance which leads to a concussion, resulting in a worsening baseline of balance? Or does the poor balance result from sustaining a concussion, or more likely multiple concussions? For these types of questions to be properly addressed, a longitudinal study would need to be completed, starting with kids, prior to collision sport participation." 

Sources:

Miyashita TL, Diakogeorgiou E, Marrie K. Correlation of head impacts to change in balance error scoring system scores in Division I Men's lacrosse players. *Sports Health* 2017 Jan 1. *IEpub ahead of print*

Plisky PJ, Rauh MJ, Kaminski TW, Underwood FB. Star Excursion Balance Test as a predictor of lower extremity injury in high school basketball players. *J Orthop Sports Phys Ther* 2006;36(12):911-919.



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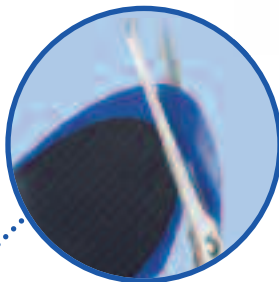


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3D PRINTING OF FOOT ORTHOSES:

Clinical feasibility and cost-benefit analyses

Several technical issues currently limit the cost effectiveness of 3D-printing custom foot orthoses, but these will likely be addressed in the near future with the emergence of larger and faster 3D printers.

By Steven Hoeffner, PhD; Timothy Pruett; Breanne Przechelski, MS; Brian Kaluf, CP; Nikki Hooks, CO; Katelyn Ragland; Shannon Hall; Kyle Walker; Dan Ballard, CPed; and John DesJardins, PhD



Table 1. Summary of Print Technologies and Print Materials Applicable to Foot Orthotics

Printer Type				Print Material										
Print Technology	Description	Build Box Size, Inches	Printer Cost	Ref	Type	Shore A Hardness	Tensile Strength, Mpa	Tensile Modulus, Mpa	Elongation at Break, %	Density, g/cm ³	Gross for Base	Cost, \$/kg	Ref	
														Commercially Available Now
UV Cured	Inkjet print head jets proprietary photopolymer material into thin layers onto a build tray. Each layer is cured by UV light. Gel like support material is removed by water washing.	11.8 x 7.8 x 5.9	\$45,900	9	UV cured acrylate photopolymers + support material	75-77	5-5	—	45-55	1.125	300	\$330.00	2	
						—	—	—	—	—	300	\$330.00	20	
Fused Filament Fabrication (FFF)	A rigid thermoplastic filament is fed through a heated extruder head. Once cooled the thermoplastic sets.	12 x 12 x 12	\$6,095	11	Thermoplastic Polyurethane	85	20	12	600	1.190	317	\$86.65	1	
						82	35	—	700	1.245	324	\$79.45	13	
		12 x 8 x 12	\$5,890	12	Polyurethane-elastomeric polymer and poly-PVA	40-60	—	—	—	—	—	300	\$100.00	4
						86	52	51	550	1.200	320	\$58.00	24	
Stereolithography (SLA)	UV laser causes chains of molecules in a photopolymer resin to link together, forming a solid, layer by layer.	13.0 x 9.7 x 2.2	\$40k/yr	14	Polyurethane elastomer	55-60	5-7	6-8	250-300	0.985	300	\$252.54	6	
Selective Laser Sintering (SLS)	Plastic beads are fused together by heat from a high power laser forming a solid, three-dimensional part.	15 x 15 x 15	\$375,500	15	Thermoplastic Elastomer Powder (polyamide)	45-75	1.8	7.4	110	1.200	320	\$174.35	3	
Commercially Available in 3-5 Years (Estimated)														
FFF w/ Screw Extruder	FFF Printer modified to work with multi-screw extruder feed	12 x 12 x 12, assumed	\$125,000, est	7	Thermoplastic (copolymers)	52	10-34	—	>600	0.900	240	\$10.79	22	
						32	20	—	1500	0.920	215	unknown	22	
						5	0.16-0.68	—	700-800	0.890	212	\$132.15	23	
Subsurface Catalyzation	A catalyst is injected into a bed of silicone oil, cross linker and thickener causing localized curing.	12 x 12 x 12, assumed	\$175,000, est	8	Room Temp Vulcanizing (RTV) Silicone Polymer	10	—	—	—	1.000	268	\$8.48	5	

Printer cost + (Printer cost*.06**7) + (Washer or Oven)

Cost for a pair of orthoses = $\frac{\text{Printer cost} + (\text{Printer cost} \cdot 0.06 \cdot 7) + (\text{Washer or Oven})}{\text{Total \# pairs of orthoses printed over 7 years}}$ + (Labor + materials + electrical) per pair

During the 2016 Olympic Games in Rio de Janeiro, many of the athletes competed wearing custom 3D-printed athletic shoes, and researchers are developing new applications for 3D printing technology every day. 3D printing technology holds great potential for creating custom devices that interface with the human body, including custom foot orthoses. But the feasibility and cost-benefit ratio associated with investing in these novel technologies and equipment must be better understood for 3D printing technology to bridge the gap between R&D and clinical practice.

The Orthotix research group at Clemson University in South Carolina has focused on the feasibility of 3D printing while innovating new approaches to create custom foot orthoses for persons with diabetes. Students at Clemson have demonstrated the structural viability of the rapid fabrication of custom foot orthoses using 3D-printed ultraviolet (UV)-cured resin materials.¹ However, the cost to fabricate orthoses using UV-cured resin printers is significantly more than the cost of traditional orthoses. Orthoses printed with 3D printing technology cost about \$300 to \$400 per pair compared with \$60 to \$80 for traditional orthoses.¹

3D printing of custom orthoses has advantages over traditional orthotic manufacturing: 3D printing can produce custom shapes and geometries not possible through traditional fabrication techniques, devices can be made more quickly and are easier to modify and reproduce, and a permanent digital record is generated for all orthoses and any changes. The cost, however, will need to be lower for this device fabrication approach to be viable.

3D printing continues to evolve, and it should be possible, now or in the near future, to fabricate custom orthoses using lower-cost 3D printers and print materials. An understanding of the possibilities and limitations of additive manufacturing, including fabrication costs, can help lower extremity practitioners make more informed decisions when contemplating 3D printing of custom prosthetic and orthotic devices.

Identifying 3D printing needs

Two key criteria for 3D printing of custom foot orthoses include build box size (ie, the volume available for printing, measured in length, width, and height, that is the maximum size of an object a 3D printer can produce) and the hardness of the materials used for fabrication. A relatively large build box (12" long x 4" wide x 1" high) is required to print foot orthoses that will fit in shoes up to men's size 11. This constraint eliminates many commercially available printers and can significantly affect printer cost. In addition, a print-material hardness of Shore A85 or less is needed.² Softer areas can be produced by printing in a pattern that introduces voids, or areas without print material, into the print product.

Material strength and other properties will also need to be considered, but acceptable tests and values have yet to be defined. Other qualifiers could include flexural modulus, tear resistance, toughness, impact strength, impact resistance, abrasion resistance, and UV resistance.

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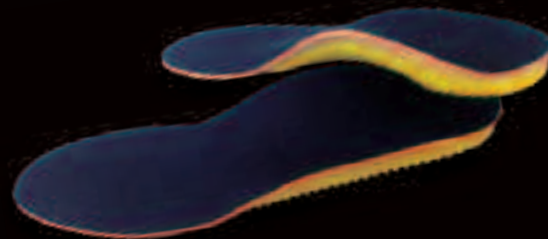
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Table 2. Summary of Amortized and Fixed Costs for 3D Printing of Foot Orthoses							
	FFF#1	FFF#2	FFF-SE	SSC	SLS	SLA	UV Cure
Printer	\$4,095	65,995	\$125,000	\$175,000	\$375,000	620,000	\$84,900
Printer + Maint Contract	\$5,815	\$5,673	\$177,500	\$244,500	\$532,500	\$280,000	\$52,571
Cost per Pair of Orthoses							
Consumables + Labor	\$76.57	\$102.19	\$40.86	\$73.40	\$177.21	\$182.83	\$321.09
Labor	\$14.67	\$14.67	\$14.67	\$14.67	\$14.67	\$14.67	\$14.67
Consumables	\$55.90	\$87.52	\$25.20	\$58.73	\$122.54	\$168.16	\$306.43
Total Cost to Print a Pair of Orthoses							
4 prints/wk	\$71.26	\$104.81	\$13.04	\$73.40	\$255.74	\$217.45	\$345.43
10 prints/wk	\$71.65	\$102.24	\$73.74	\$59.41	\$235.52	\$214.70	\$330.83
21 prints/wk	\$71.67	\$102.68	\$56.27	\$44.97	\$185.69	\$207.16	\$325.66
% (Consumables + Labor) to Print a Pair of Orthoses							
4 prints/wk	104%	102%	301%	99%	280%	17%	108%
10 prints/wk	102%	103%	180%	29%	172%	138%	103%
21 prints/wk	103%	100%	138%	19%	134%	113%	101%

3D printers are designed to print certain types of materials, but within a given print technology, there can be a range of material properties; for example, fused filament fabrication (FFF) materials can be acrylonitrile butadiene styrene (ABS) or polylactic acid (PLA). Several print technology options are available for 3D printing of custom foot orthoses, and more options may be available soon.

Currently available options

Printing using UV-cured resins. An inkjet print head jets proprietary photopolymer materials in thin layers onto a build tray, layer by layer. Each layer is cured by UV light. Gel-like support material is removed by water jetting. (Because of the nature of certain types of 3D printing and the geometry of the part being printed, structural support of the part may be required during the printing process.) These

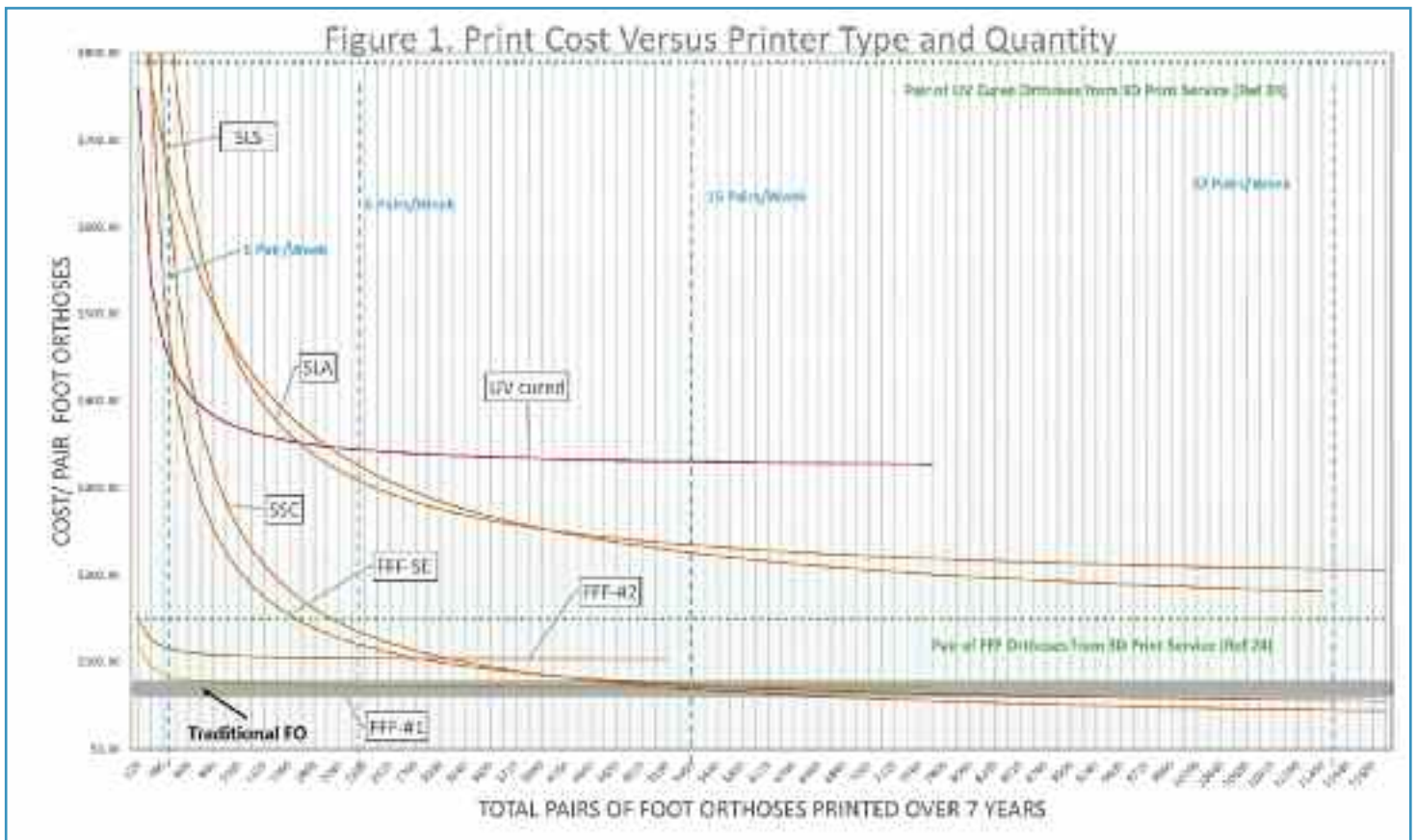
systems can currently produce a material with a Shore A hardness of 26 and higher.³

Printing using thermoplastic filaments.

FFF printers use a rigid thermoplastic filament that is fed through a heated extruder head. Once cooled and set, the materials are typically fairly rigid or hard. The filament must have some rigidity so it does not buckle when being fed into the heated extruder head, and so the feeding rollers or gears can grip the filament. This limits how soft the filament can be, typically a Shore A hardness in the mid 80s, though new materials continue to come out. For example, we recently purchased and successfully printed a material with a reported Shore A hardness of 40.⁴ Another recent material is part rubber-elastomeric polymer and part polyvinyl alcohol (PVA).⁵ The PVA dissolves during a one- to four-day water soak, and the remaining material has a Shore A hardness of 40 to 60.

Printing using thermoplastic elastomers. Using selective laser sintering (SLS), plastic beads are fused together by heat from a high-power laser to form a solid 3D part. These systems can currently print materials with a Shore A of 45 to 75.⁶

Printing using high performance polyurethane elastomers. Using stereolithography (SLA) printing, a vat of liquid photopolymer resin is cured by UV laser, solidifying the pattern layer by layer to create the solid 3D model. This process is similar to UV-cured resin printing, but a key difference is that laser printing occurs layer by layer, which can be much faster than the line-by-line process of



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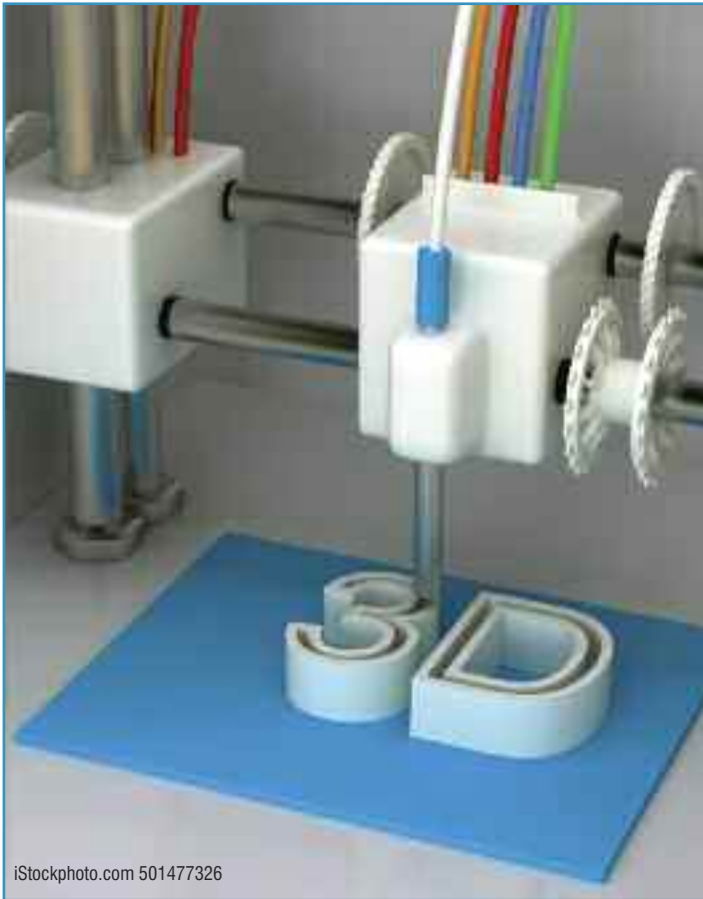
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UV-cured printing. The process includes a postprinting curing step that appears to improve the properties of the final product. These systems can currently print materials with a Shore A hardness of 55 to 60.⁷

Options that may soon be available

Printing using low Shore A thermoplastic elastomer (TPE) materials. Modifying the print head from a filament line feed to a miniscrew extruder (FFF-SE) allows a 3D printer to use pellets of very soft thermoplastic elastomer materials.⁸ An advantage of this approach is that potentially any TPE material could be used (eliminating the need to use proprietary materials), and these printed materials have superior mechanical properties, such as tensile strength and elongation to break, compared with UV-light cured photopolymers. This type of printer is not yet commercially available, but it could be within the next three years. In early trials,⁷ materials with a Shore A hardness as low as 5 were printed.

Printing with silicone rubber. Using subsurface catalyzed (SSC) printing,⁹ a catalyst is injected into a bed of silicone oil, cross linker (which controls the product's softness), and thickener. The catalyst causes localized curing, forming the room temperature vulcanization (RTV) silicone product. The resolution is low, but may be adequate for orthoses. The raw materials are inexpensive. The printer is not commercially available, but could be within three to five years. This technology can produce very soft materials (Shore A hardness of 10 and less).

Costs of printing foot orthoses

Printers using one of the technologies/print materials identified above can likely print foot orthoses of acceptable build box size and material

hardness (other criteria such as durability are currently being evaluated and will be added as this application area matures). Costs associated with the following 3D printing options were analyzed:

- UV-cured printer¹⁰ producing photopolymer material¹¹
- FFF printers^{12, 13} producing TPE¹⁴ and PVA⁵
- SLA printer¹⁵ producing polyurethane elastomer⁷
- SLS printer¹⁶ producing thermoplastic elastomers⁵
- SSC printer⁹ producing RTV silicone
- Custom FFF-SE⁸ producing TPEs

Table 1 provides a summary of representative printers and print materials from each of these technologies and includes printer cost, printer build box size, and the cost of print materials and some material properties. Printer costs were obtained from a 2015 Wohlers Associates report on 3D printing.¹⁷ For the printers not yet commercially available, \$125,000 was assumed for the FFF-SE printer and \$175,000 for the SSC printer. Build box size determined the number of orthoses that could be printed per run (typically three, and sometimes two single orthoses).

The information used to calculate the cost to print foot orthoses includes the cost of the printer, annual maintenance contract, consumables (print material and, if needed, support material), electricity, and labor. A pair of orthoses require 600 g of UV-cured print material and 600 g of UV-cured support material. Densities were used to estimate the amount of print material required when using other print technologies. Electrical consumption was obtained from printer specifications. Pre- and postprinting labor was estimated to be .2 hours at \$55 an hour for all printers. Excluded were lower-cost items that had minimal impact on overall cost, such as solutions that dissolve support material, FFF build sheets, injector tips or print heads, and other replacement parts).

A seven-year life span was assumed for all printers. Washer and oven cost (for postprocessing on some print technologies) was set at \$3000. These costs, along with the annual maintenance contract (6% of printer purchase cost), were amortized over the seven-year printer life. A 10% contingency was added to the final total cost.

Cost for a pair of orthoses was calculated as:

$$\frac{\text{Printer cost} + (\text{printer cost} \times .06 \times 7) + (\text{washer or oven cost})}{\text{Total \# pairs of orthoses printed over 7 years}} + (\text{labor} + \text{materials} + \text{electrical}) \text{ per pair}$$

The results, shown in Figure 1, provide a convenient way to compare the cost of printing materials using different printers as well as the costs of in-house printing, third-party printing, and traditional foot orthoses. The denominator (total pairs of orthoses printed over seven years) varied; all other values were fixed.

Included in Figure 1 are:

- The cost curves for the six different print technologies/materials (two different printers and materials are shown for the FFF technology) as a function of the total number of pairs of orthoses printed over the seven-year printer life;
- The equivalent number of pairs of orthoses printed per week (blue text and vertical dashed lines);
- The number of traditional pairs of orthoses produced by Upstate Pedorthic Services, a regional pedorthic practice (blue text box);
- The cost a clinician pays for a traditional pair of orthoses (\$60-\$80, gray horizontal shaded band);
- The cost a clinician would pay to for a pair of 3D custom orthoses made by a company that provides 3D printing services (green

Continued on page 24

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horizontal dotted lines, two different printer technologies/ print materials); and

- Maximum printer capacities (the point at which the curves end)

Currently, only the FFF technologies are price-competitive with traditional foot orthosis manufacturing (horizontal gray shaded band). In addition, FFF printers are low cost, materials are moderate to low cost, many of the print materials appear to be durable, printers and materials are widely available, and percent infill can be

varied to change the softness of the printed material. In the longer term, FFF, FFF-SE, and SSC all appear promising from a cost perspective.

For any volume greater than a couple of pairs of orthoses per week, it is more cost effective to 3D print the orthoses in house than to have them made by a 3D print service (horizontal green dotted lines). This assumes the 3D printer employee can continue to bill for other services with his remaining time.

Print speed is not a significant cost discriminator. Print speed is determined by multiple factors: print technology, bed size, support material needs, and in some cases, even software.¹⁶ Printer speed for similar technologies (eg, those that print line by line) is mainly determined by bed size. And which print technology is fastest can change as conditions change.¹⁹ In general, print speeds for most technologies (except for the SLA printer, which can be up to 25 times faster) are all relatively comparable. For example, it takes eight hours to print three orthoses using a UV-cured resin printer and 12 hours to print the same orthoses using an FFF printer. Although print speed determines the ultimate limit on the number of orthoses that can be printed, Figure 1 indicates unit cost is determined more by the amortized cost of the printer and the cost of print materials than by print speed (indicated by the total number of pairs of orthoses printed).

A single printer may not be adequate to meet demand. One printer (with the possible exception of the SLA printer) could not print all of the 70 pairs of



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orthoses per week prepared by Upstate Pedorthic Services. The UV-cured resin printer can generate about 45% of this amount, the FFF printers, 30%. Having two or more printers may be an option, especially with the low-cost FFF printers.

Table 2 summarizes the amortized and fixed costs of 3D printing foot orthoses. The table indicates that, based on the cost of materials alone, the UV-cured, SLA, and SLS technologies are currently all more expensive than traditional orthotic manufacturing. Proprietary technologies and print materials always command a premium; as a result, at this time, custom foot orthoses made using these technologies are \$300 to \$400 a pair when the costs of labor, supplies, and consumables are included. In contrast, the technologies that use nonproprietary print materials show significant promise from a cost perspective, especially FFF.

Summary


There are several materials (and different associated 3D printer technologies) that could be used to 3D print custom foot orthoses. This list will continue to grow as the field develops and matures. Some of the technologies presented here are not yet commercially available, but could be in the next few years. At this time, only FFF technologies have the potential to be price-competitive with the cost of traditionally manufactured custom foot orthoses.

Build box size is a significant factor in determining which printers are acceptable. For many of the available printers, the build box is too small for printing orthoses.

The ability to use nonproprietary materials helps significantly decrease the cost of 3D printing foot orthoses. The FFF technology, printers, and print materials are especially attractive.

The cost of 3D-printed orthoses is determined mainly by amortized cost of printer and the cost of print materials, and less by printer speed. For anything more than a couple pairs of orthoses per week it should be more cost effective to print them in house than to have them made by a 3D print service.

Conclusion

After examining factors that influence the cost-benefit ratio and feasibility associated with new 3D printing equipment, it is apparent there are still several technical limitations to printing custom foot orthoses. These limitations may be overcome, however, and the associated costs reduced, as the technology becomes more common and as future innovations produce larger and faster 3D printers. 

Steven Hoeffner, PhD, is the owner of Hoeffner Consulting in Easley, SC, and has experience applying different 3D printing technologies. Timothy Pruett is a member of the Machining and Technical Services staff, and Breanne Przestrzelski, MS, is a PhD student in the bioengineering program at Clemson University in South Carolina. Brian Kalu, CP, is the clinical outcomes and research director at Ability Prosthetics and Orthotics in Exton, PA. Nikki Hooks, CO, is an orthotist and board-eligible prosthetist at Ability Prosthetics and Orthotics, and is on the board of directors for the Orthotic and Prosthetic Activities Foundation in Charlotte, NC. Katelyn Ragland, Shannon Hall, and Kyle Walker are undergraduate bioengineering students at Clemson University. Dan Ballard, CPed, is a pedorthist at Upstate Pedorthic Services in Greer, SC. John DesJardins, PhD, is the Robert B. and Susan B. Hambricht Leadership Associate Professor of Bioengineering at Clemson University.

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Does history of running protect against knee OA?

Running may increase the risk of knee osteoarthritis (OA) onset or progression for some people, but in many others the knees will be safe during running; in such individuals, the benefits of physical activity can positively affect weight management and other means of reducing OA risk.

By Nicole M. Cattano, PhD, LAT, ATC; and Jeffrey B. Driban, PhD, ATC, CSCS

Osteoarthritis (OA) is a complex joint disorder defined by structural changes, pain, and other symptoms. People often describe OA as “wear and tear” of the joint. OA often affects weightbearing joints such as the knee and hip. Researchers and clinicians commonly debate whether running is good or bad for joint health.^{1,2} Some say the repetitive “pounding” of running increases the risk of lower extremity OA,¹ while others note the benefits of running (eg, maintaining a healthy body weight, improved function) that may reduce the risk of OA².

As with many things, the answer is not just black and white. After all, if you excessively drive your favorite car for years, it will eventually break down and you will need to replace it. Conversely, if you leave your car parked on the street for a year and never use it, then you will have problems with it, as well. This analogy can also be applied to the joints of the body, and finding the right balance is critical to long-term joint health. If you overdo it, you ruin it—but if you don’t use it, you lose it.

Using it vs overdoing it

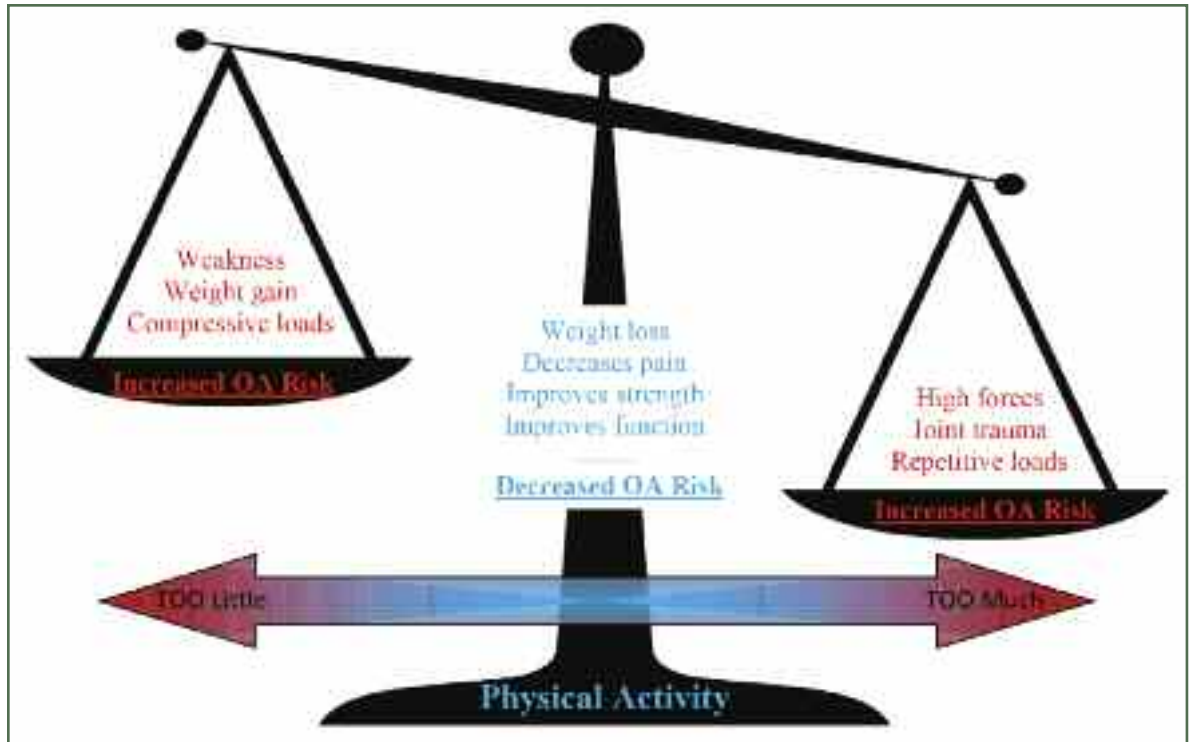
There is a delicate balance between joint tissue remodeling and loading, and maintaining this balance is critical to joint health. Research suggests deviation from this homeostasis is associated with OA onset and progression (Figure 1).

Although physical activity is a major component of joint health, this relationship can also be confounded by other things, such as a history of joint injury. Animals that have been casted or immobilized demonstrate cartilage changes and OA onset;^{3,4} suggesting that if you don’t use it, you lose it. Physical inactivity and obesity are also associated with more severe pain in patients with knee OA.⁵

Conversely, research also suggests that if you overdo it, you ruin it. Animals that perform highly repetitive activities had more joint inflammation than those who were less active, along with early cartilage changes indicative of OA onset and progression.⁶⁻⁸ These highly repetitive activities also caused a decrease in animal strength

Clinically, it is important to understand that gradual increases or changes in training will allow the tissues time to adapt to load in a healthy manner and reduce the risk of OA.

Figure 1. Maintaining a balance between joint tissue remodeling and loading is critical to joint health. Research suggests deviation from this homeostasis is associated with OA onset and progression.



and performance over time, likely due to increased symptoms and subsequent pain avoidance.⁸ Although pain avoidance may seem to be a good thing, it can actually cause more harm. Changes in motion can shift loads to other areas of the body that are not used to sustaining such loads and ultimately increase OA risk at other joints, in addition to the involved joint.

Similar results have been observed in humans. For example, elite skiers, who train and compete more often than less competitive peers, are at higher risk for hip or knee OA.⁹ Furthermore, elite long-distance runners are more likely than nonathletes to develop knee OA.¹⁰ This indicates excessive overloading may be an important risk factor for lower extremity OA. Although elite-level sport participation may be associated with a higher risk, it remains less clear whether it is the peak loading forces or the repetitive forces experienced over time that contribute to this increased OA risk.

Peak loading vs cumulative loading

Excessive peak force through a joint may cause pain and ultimately increase the risk of injury and long-term complications. However, the relationship between peak loading and symptoms can change based on knee OA severity.¹¹ In patients who had moderate knee OA, greater peak load was associated with increased knee symptoms. However, researchers found the opposite in patients with advanced knee OA, in whom greater peak loads were associated with fewer knee symptoms. The findings of this study may be related to pain avoidance patterns or changes in joint integrity and structure.

The quality of joint motion over time, and how the forces are dispersed across a joint throughout every step of the day, may be better related to the “wear and tear” associated with OA. Therefore, cumulative loading, or loading over time, may be more important than peak loading when considering OA development. Researchers found no differences in peak adduction load between patients with and without knee OA. However, they reported cumulative knee adductor load was more accurate in distinguishing adults with and

without knee OA than measuring peak adduction moment alone.¹² Cumulative knee adductor load (the sum of the amount of knee adduction experienced throughout all steps in the course of a day) was twice as high in patients with knee OA compared with patients without knee OA.¹² This supports the hypothesis that patients with knee OA move differently than patients without knee OA, and could be associated with changes in symptoms or pain-avoidance patterns. Several things may influence cumulative loading and joint health, such as the intensity of loading, the frequency of loading, the duration of activity, as well as rest for recovery. Sudden or drastic changes in any of these components could influence how a joint tolerates loading.

A person’s regular physical activity level may reflect the amount of load a joint typically experiences and may determine a threshold for how much load a joint can tolerate. For example, a group of highly active individuals had no biochemical marker changes associated with cartilage breakdown after a light 30-minute run.¹³ In a separate study in which participants were analyzed based on reported physical activity level, more active individuals had smaller increases in cartilage degradation markers after a 30-minute run than less active individuals.¹⁴ This evident dose-dependent response suggests the running task was not difficult enough to cause joint stress and metabolic changes in this highly active cohort. Clinically, it also suggests individuals can gradually train their bodies to sustain running loads in a healthy manner.

The dose of the physical activity experienced by an individual may influence joint metabolism and, ultimately, long-term joint health. Walking and running cause temporary biochemical changes reflecting cartilage turnover that return to baseline levels within a couple of hours.¹⁵⁻¹⁸ These changes are elevated more drastically and take longer to return to baseline with longer-lasting activities, such as a marathon or ultramarathon.^{19,20} Body weight and altered

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biomechanics can also adversely affect joint loading. Walking with a greater body mass was associated with greater increases in cartilage degradation, which took longer to return to baseline than in individuals with lower body mass.²¹

Running and cartilage load

Training interventions appear to mitigate the changes in joint metabolism observed after a running task. After a 12-week running program the increases in biochemical makers of cartilage turnover that were previously seen after a 30-minute walking activity were drastically reduced; similar reductions were not seen in individuals who had completed 12 weeks of swimming or cycling.¹⁶ This suggests the running program allowed joints to adapt over time to be able to withstand a running load. Clinically, it is important to understand that gradual increases or changes in training are needed to allow the tissues time to adapt to load in a healthy manner.

If a person runs consistently throughout their life while avoiding joint injury or sudden changes in running intensity, duration, or frequency, then the benefits of running likely outweigh the risks of developing OA. In a large cohort of adults, those who reported a history of running were no more at risk for OA than those who had no history of running.²² Habitual running may in fact reduce the risk of OA by helping individuals maintain a healthy weight and body mass index. People who

reported a history of running were likely to have a lower body mass index than nonrunners, and we believe this relationship may be protective against OA development and progression.²²

Although most people tolerate running well, this may not always be the case. Highly active people who reported lower quality of life had greater increases in inflammation after a 30-minute run than those whose quality of life was better.¹² People who have advanced-stage OA (bone on bone) may need to be cautious with their weightbearing physical activities to avoid worsening symptoms.²³ Also, as noted above, elite long-distance runners may also be at risk for knee OA. However, for these elite athletes, it remains unclear if their risk for OA is because of the high mileage or frequency of their training, their history of injuries, and/or their management of those injuries (eg, running with pain or returning to sport too early). Most of the evidence relating a history of sport participation to lower extremity OA is of low quality and is almost exclu-

sively based on data from men, despite women representing a large portion of the US athletic population.^{10,24} In two recent systematic reviews, researchers reported injury may be a major influence that explains why some elite athletes are at higher risk for OA, especially in soccer.^{10,24}


Finding a balance

The Physical Activity Guidelines Advisory Committee provided overwhelming evidence in its 2008 report to support a physically active lifestyle.²⁵ These findings included the conclusion that a physically active lifestyle does not increase OA risk. However, the expert panel's findings regarding OA risk do not necessarily apply to elite-level or extreme athletic activity. Finding an appropriate balance in activity may be critical to joint health. Clinicians should encourage patients to be physically active, and when there is concern about a person's risk for OA onset or progression, they should promote forms of physical activity, such as swimming or moderate running, that are less likely to increase that risk. After all, exercise is a common component of OA treatment guidelines and a key to long-term wellness.²⁶

Clinicians can use what is known about physical activity



and OA to help educate patients about long-term joint health. However, self-reported physical activity levels may not be accurate enough to rely on independently. Patients with OA overestimated their self-reported moderate to vigorous physical activity minutes by an average of seven minutes compared with objective data from an activity accelerometer.²⁷ Clinicians and patients should carefully monitor symptoms in addition to physical activity levels; patient-reported outcomes may help identify people who are putting their joints at risk. Although running may increase the risk of OA onset or progression for some people, many people will be safe running and will gain the well-documented benefits of physical activity, which can be a positive strategy for weight management and other means of reducing OA risk.

Finding the appropriate balance of physical activity is critical to long-term health. Educating our patients about risks and healthy lifestyles will help them in their long-term battle to prevent OA onset and progression. Paying attention to joint symptoms, current physical activity levels, and making gradual changes to training programs will assist in efforts to live a healthy and pain-free life. 

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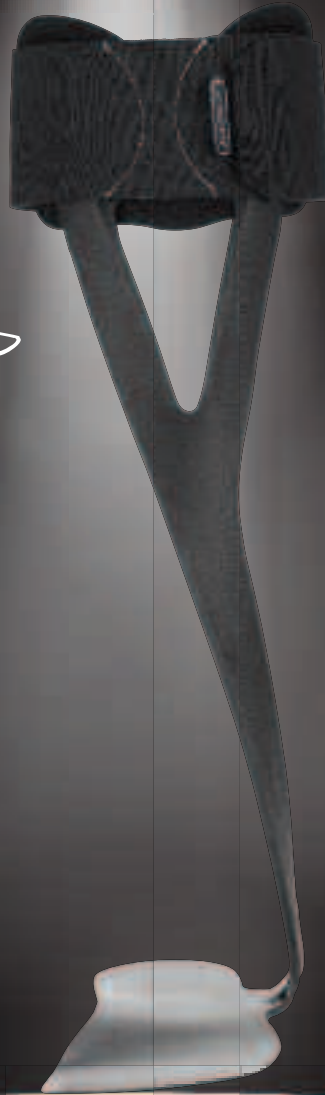
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Managing O&P patients who are hard on devices

Even patients who obediently wear their O&P devices can pose a clinical challenge if they wear their devices past the point of breakdown. Experts offer suggestions for dealing with patients who are hard on devices—including those who are very large, very active, or very frugal.

By Shalmali Pal

Managing adult patients who are noncompliant with their O&P devices is a persistent problem for lower extremity practitioners. But what about a patient who willingly complies with her prescribed device—and then uses it to the point that could verge on device abuse?

For instance, there is the patient with a custom foot orthosis who will wear the insert until a hole appears in the bottom—and then duct tape the hole up and continue using the device. Then there is the patient who reports no “unusual” changes to his daily activities with the device on, only to eventually inform the practitioner that its harvest time in his agricultural community, so he’s been wearing the device for 12-hour days. Or the patient in his early 20s with an ankle foot orthosis (AFO) who spends his weekends at clubs slam dancing (in which people deliberately collide with each other), device and all. Finally, there is the patient with diabetic neuropathy who doesn’t feel the discomfort caused by a damaged brace, and continues to wear the device in its distressed state.

No one could accuse these patients—all real people encountered by the experts *LER* spoke with for this article—of being non-compliant. They happily wear their devices, and go about living their real lives. But a prescribed device, whether an AFO, knee brace, or foot orthosis, can only take so much “reality” before it begins to break down, potentially putting the user at some health risk. A device works best when it is worn, but also when it is worn properly and cared for. All of this means practitioners need to fit a device in more ways than one.

“It is crucial that practitioners understand as much about a patient’s past, current, and expected levels of function as possible before formulating a treatment plan,” said John T. Brinkmann, CPO/L, an assistant professor with the Northwestern University Prosthetics-Orthotics Center in Chicago. “Revisiting this issue is important during subsequent appointments, since use patterns change significantly and patients may not think to include relevant information when asked about their function. This requires good interviewing skills,

Clinicians should try to understand as much as possible about a patient’s past, current, and expected levels of function before formulating an orthotic treatment plan.



Photo courtesy of Kinetic Research.

which includes listening closely for clues about what to ask more about.”

Why the wear and tear?

There are a variety of reasons that a patient may put a device under excessive duress. Patient size—which can be related to obesity or excess weight, muscularity, or an otherwise large body habitus—and abnormal biomechanics (eg, spasticity, contracture, malalignment) are the perhaps the easiest for practitioners to oversee.

Practitioners will need to make accommodations for these issues before prescribing and fitting a device, and adjust the type of material used in the device to handle any excess loading, whether that’s from weight or abnormal biomechanics, said Linda Laakso MSc, CO(c), a staff orthotist at Custom Orthotic Design Group in Mississauga, Canada.

“The design of a brace will affect how it wears, and by using certain design characteristics, a brace can be stronger, lighter, more streamlined—all criteria that are identified during an assessment and incorporated into the brace,” Laakso said. “An example would be to increase the amount of plastic that covers the uprights and joints to make them stronger versus cutting the plastic back to make the brace lighter.”

Brinkmann agreed that a full discussion with the patient on how the extra weight will impact the device needs to take place. For instance, devices can be modified to withstand greater maximal loads or made more durable.

“However, those strategies come with a cost—the device is usually more heavy and bulky, or may require the use of more expensive

components,” he explained. “Part of the clinical decision-making process is to balance these patient needs that are often competing. Making sure that the patient understands the potential consequences of any design decision, and has a say in the process, is an important part of effective clinical decision-making.”

Rob Conenello, DPM, a podiatrist with Orangetown Podiatry in New York, and a past president of the American Academy of Podiatric Sports Medicine, said he will emphasize that the device is an important aspect of any healthy lifestyle plan.

“We are giving them a device that helps them be active in a better way, so that they can reach the goal of being fit,” Conenello said. “However, I also explain that when there is a greater demand on the device, the likelihood that the device will break down is greater.”

Another reason a patient may put a device through the ringer is because they are frugal or simply don’t make caring for the device a priority. These patients can be a little tougher to manage, but there are ways to get the message across that no device will last forever.

“After we do an initial assessment, we would describe our recommendations, the design of the brace, and what to expect,” Laakso said. “Part of that discussion is how long it takes to get used to the brace, how long it may take to notice a change, and how long the brace usually lasts.”

For instance, most long leg braces or KAFOs last three to five years, as long as there hasn’t been a change in medical condition, a change in a person’s size or shape, or trauma to the brace, she said. But Laakso will also emphasize that a device’s lifetime may vary, based on usage and care.

Laakso authored a page on the Custom Design website that details the appropriate use and care of orthotic devices, such as “Do not exercise with FOs [foot orthoses] within the 2 week break-in period” and “DO NOT dry the orthosis with a hair dryer. Wipe it dry with a towel,” in reference to AFOs or knee braces.¹

She emphasized patients still need to be briefed individually on how to care for the devices, even if they’ve had plenty of prior experience with them.

“We also look at the cognitive abilities of the person with respect to being able to follow instructions—very detailed but simple written instructions are given to some people, while a seasoned brace wearer would have a review of the process [or a teach-back method],” she said. “We also would book more frequent follow-ups for people that we are concerned about. The teaching sessions will occur either in full or as a reminder at each visit, as well.”

In the teach-back method (also known as the “show-me” method), the patient is asked to repeat what the practitioner has just demonstrated or explained, to show he or she has understood instructions.

Clinicians should help patients on a tight budget understand that caring for a device increases the chance that it will last for its expected lifetime, the experts stressed.

“I always stress, ‘This is a very important piece of medical equipment that is going to help you. If you treat it well, it will treat you well. Clean it fairly regularly to get rid of dirt and sweat. Take it out of the shoes on a daily basis and let it air dry. If there’s a Velcro closure, try to keep it relatively free of pet hair or lint.’ But I also explain that the device is not going to last forever,” said Conenello, who is a global clinical adviser to Special Olympics International.

David Armstrong, DPM, MD, PhD, a professor of surgery at the

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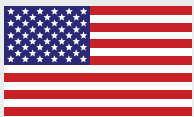
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University of Arizona College of Medicine, and director of the Southern Arizona Limb Salvage Alliance (SALSA) in Tucson, AZ, pointed out that patients may avoid getting a new device because of financial hardship.

“Devices can be costly, and we are still seeing poor insurance reimbursement for the device makers,” he said. “That’s just one of many problems with our current healthcare system, but we have to do something to help these patients. What it really mandates is that the clinician and the entire care team, including those who help with coverage, work together to figure out how to help these people live their ‘normal’ lives.”

There will always be people who wear a device long past its “use by” date, and practitioners may have to accept that their control of the situation will have limits.

“When we see obvious defects, we try to fix them, and if we cannot, we advise the patient to not wear the brace due to the risk



Photo courtesy of Townsend Design.

of injury," Laakso said. "I take time to explain potential consequences and suggest a new brace. Since I am not there to watch over people, I suspect that some people do not listen to my recommendations and wear the brace anyway."

On the go

Very active patients generally fall into two categories—those whose professions are physically demanding and those whose extracurricular activities involve a lot of physical movement, whether related to sports, fitness, the outdoors, or travel.

Many of Conenello's patients are high-intensity athletes, so their devices wear out sooner rather than later.

"I work with some ultramarathoners, cross-county runners. It's a given that their devices will get beat up quicker," he said. "I explain that they are really going to have to spend the time to keep the devices clean and dry. Sometimes we'll incorporate moisture-wicking products into the devices to help with that." (See "Materials science targets foot odors and microbes," *LER Foot Health*, June 2016, page 21).

Other "obvious" candidates for being tough on devices are patients whose jobs involve manual labor, or require that they spend long periods on their feet. Experts agreed practitioners must get data on a patient's normal activity levels before the device is even fit.

"It is very important to know the activities that the person will be performing before the brace is made so that materials and design factors can be considered when planning the brace," Laakso advised. "For example, the brace that I make for a twenty-two-year-old who goes to school every day...would be different from the brace that I would make for a sixty-five-year-old who...only goes out for groceries once a week, even if the weight and size of the two people are the same."

And bear in mind that a practitioner and a patient may have different definitions of what constitutes normal use or unusual activity.



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"I've been in encounters where patients said they had not changed their wear pattern, only to find out several questions later that they began walking on a treadmill for exercise earlier that week,

or doubled their daily wear time because it was harvest season," Brinkmann noted. "The patients in each of these situations considered their activity 'normal' and not worth mentioning when asked, 'Have you been doing anything unusual in the past week?'"

So, how can practitioners ensure that they get as much valid information as possible? By asking questions about normal or unusual activity at the first fitting, and then continuing to ask at every follow-up appointment.

Brinkmann suggested rephrasing a question if the initial answer seems too vague.

"In both of these cases, if I'd given up after asking only once about any change in their activity level, I wouldn't have gotten that necessary information. It really takes some creative questions and actively listening to get an accurate picture of their activities," he said.

Laakso said she will start with some general questions about expected levels of activity, which can serve as a springboard for more information, as she develops a rapport with the patient. If she runs into a patient who is not readily sharing information, she'll take a different tack.

"If they are not at all forthcoming, I explain that I can only provide treatment if I have a good idea of what they need with respect to their medical requirements in addition to their lifestyle requirements," she said. "Once I come up with a potential treatment plan, I will describe it to the person and explain why. This often results in more of a discussion where the person provides a lot more information."

At SALSA, Armstrong and colleagues have been testing out wearable tracking devices for nearly two decades to quantify patient

An advertisement for WalkOn Reaction Plus orthotic insoles. The background is a photograph of two men on a lake, one in the foreground using a paddle on a stand-up paddleboard. The text "ottobock." is in the top right. The headline "WalkOn® Reaction Plus keeps you moving!" is in red. A green circle on the left contains the text "Quality for life". Two callout boxes with dotted lines pointing to the insole on the man's foot describe features: "Lightweight, low profile and durable" and "Anterior cuff helps knee extension". At the bottom left, the website "www.professionals.ottobockus.com" and phone number "800 328 4058" are listed.

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activity. Products like phone-based activity apps can be useful to clinicians who are trying to get a handle on patient activity levels.

"We look at it as 'dosing activity,' the way we would dose a drug," Armstrong explained. "With drugs, you have a peak and a trough—if a dose is too high, there can be adverse effects, but if it's too low, the drug may not be effective. We're always looking for that 'sweet spot.' So, if we can quantify activity through these wearables, then we can coax people into finding that same 'sweet spot' in terms of the right amount of activity [with the device]."

Having these data from wearables can also help patients identify what Armstrong called unrecognized "pockets of activity."

"The data looks a bit like an ECG [electrocardiogram] graph. We'll go over the wearable readings with the patient, and point out a change in activity level, based on the device's readout. That's when the patient will say, 'Oh, that's right, my grandchildren were visiting and we spent the day at the park. I forgot about that.'"

Laakso noted that a patient's usual activity also may include other people, and that can have an impact on a device. She shared the example of a nonambulatory, wheelchair-bound patient with bilateral AFOs (he needed them just to transfer in and out of the chair). He required a catheter that had to be changed several times a day. Unfortunately, the home healthcare workers were careless and allowed urine to drip onto the patient's braces and shoes.

"This didn't just happen once; it was over a long period of time," she said. "His braces broke down sooner because of the urine exposure. I wrote a scathing letter to the home health company. That's an example of a 'daily activity' that a patient may not think to mention."

Give and take

Adapting devices to accommodate a patient's stated (or suspected) activity level requires practitioners to think outside the box, Brinkmann noted.

"It is important for practitioners to understand optimal material selection, design features, and fabrication techniques when initially recommending a specific design, and to recognize signs of material failure and poor fit and function," he stressed. "One reason continuing education for practitioners is important is that it challenges 'the way we've always done it,' and helps us provide solutions to problems that we may have considered 'normal' in the past."

He pointed out that some of the problems with fit and component failure could be resolved with different designs and/or materials. For example, switching to prepreg carbon fiber from thermoplastics for a lower limb orthosis can render the device stronger and offers multiple benefits in terms of gait (See "Strengthening the case for carbon fiber AFOs," October 2010, page 23).

But a more advanced component, such as a carbon fiber AFO, may require some adaptation in terms of biomechanics, and patients must be educated on their proper wear and use, as the material's springy surface will push back (rather than compress) and potentially reduce the need for flexion in the hips, knees, and ankles. Patients will need to be briefed on those differences.²⁻⁴

"For example, improper ascent and descent of stairs can cause breakage," Brinkmann said. "But in general, as technology, our assessment, and the fitting process all improve, we may be able to prevent fatigue or breakage that we've come to accept as normal." (See "AFO stiffness can help optimize patient function," November 2016, page 29.)

Conenello gave the example of a very active patient with a relatively

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rigid foot, who would not benefit from a rigid, thermoplastic device.


“So I’ll utilize a more forgiving material, like an EVA or a leather laminate—something that is more accommodating,” he said. “The caveat there is that this material will not last as long, so I explain that there will come a time when we’ll have to refurbish it or change the device, and that may be sooner rather than later.”

Is there a way for practitioners to predict breakdown? Yes, to some extent.

Laakso suggested focusing on preventing “early breakdown,” versus any breakdown.

“A brace made to the individual characteristics of the patient is the most important factor in making sure the brace does not break down prematurely,” she said. “Regular check-ups and maintenance will help prolong the life of a brace. The check-ups are important to ensure that joints are properly lubricated and aligned and that there are no nicks or cracks in the plastic.”

Armstrong said the day of embedded sensors in devices that can predict some degree of device failure is not far away.⁵ These sensors can predict strain on a device or Young’s elastic modulus (the measure of a stiffness of solid materials) and communicate that information to the practitioner before it’s too late, he said.

“The advantages of the wearables plus the embedded sensor technology is that we will be able to identify failure before we even see them in the clinic. It’s like On-Star for the body,” he explained, referring to the remote-link communications systems in vehicles. 

Shalmali Pal is a freelance writer based in Tucson, AZ.

References are available at lermagazine.com.



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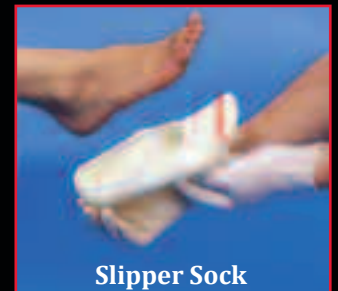
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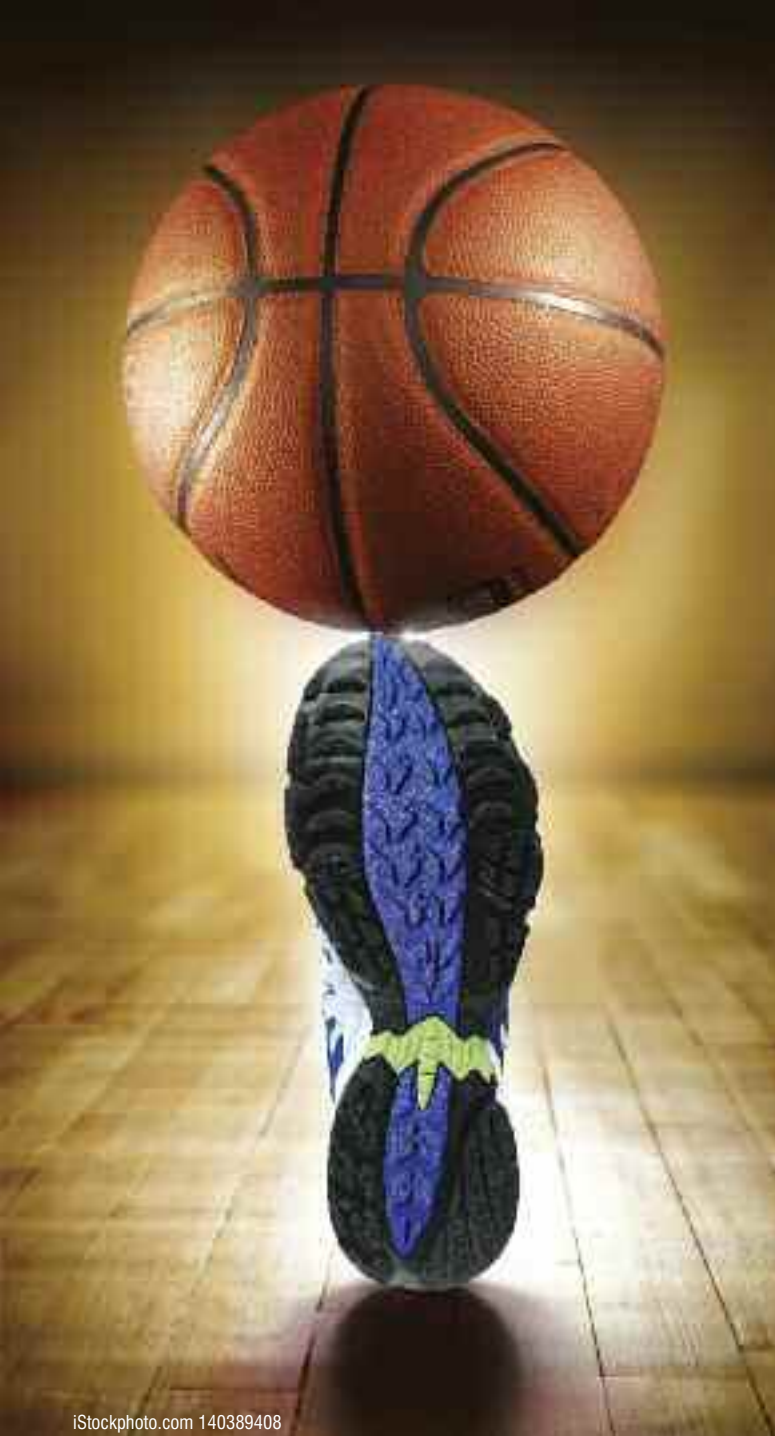
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Basketball shoe trends favor fashion over feet

Several confounding factors make it difficult to determine statistical associations between footwear and injuries in basketball, but attitudes toward shoes among National Basketball Association (NBA) players suggest both positive and negative trends with regard to potential injury risk.

By Will Carroll

There is no question that the game of basketball and the business of basketball have been revolutionized by the shoe industry. Over the last 30 years, basketball footwear has experienced a commercialization and technological advancement that hasn't been seen in any other sport at any level. Although football cleats aren't going to be worn to the club, a sweet pair of kicks from a collection endorsed by a basketball star are as much fashion staple as athletic equipment.

But the improvements in performance and function associated with basketball shoes have not led to any apparent decreases in injury rates among players, even at the professional level. Several confounding factors make it difficult to determine statistical associations between footwear and injuries in basketball, but attitudes toward shoes among National Basketball Association (NBA) players suggest both positive and negative trends with regard to potential injury risk. Many players' shoe preferences tend to be dictated by fashion, which can create fitting challenges that could potentially increase injury risks. On the other hand, many players also place a premium on comfort—in relation to both the design of a shoe and the way it is worn—which could help reduce those risks.

Some players would rather deal with injuries than change shoes. Detroit Pistons forward Stanley Johnson made headlines in October 2016 for resisting suggestions from team medical staff and Coach Stan Van Gundy that he switch shoes to help address persistent pain in his left foot, particularly when pushing off.¹ Although Johnson's shoe contract allowed him to wear any model made by Nike, he continued to wear the Kobe 11 style, named for former Los Angeles Lakers star Kobe Bryant and the third most popular shoe among NBA players at the time. Johnson insisted the Kobe 11 model was "comfortable," despite the issues. (However, in early 2017 he was seen wearing a different style, the new Kobe A.D.)

"There are often significant differences in shoes and models, both between brands and within brands themselves. Marketing drives the shoe industry, unfortunately. Because of this, there are often great-looking popular shoes supported by great athletes that

Fashion-forward preferences can create fitting challenges, but basketball players also place a premium on comfort, which could potentially reduce the risk of injury.

Shoes and injuries in basketball: In search of sabermetric answers

The lack of data on both injuries in the National Basketball Association (NBA) and on who wears what shoes creates multiple issues in analyzing the relationship. I spoke with a leading sabermetric consulting firm that deals in injury information to get the most up-to-date data. (Because they contract with several teams around the league, they asked not to be identified.)

I limited this data to the 2015-2016 season for consistency and completeness. The entire data set is fixed and most players do not change shoe models during the season, though as noted, it is impossible to completely control for this because of a lack of monitoring. During this period, the NBA had 319 injuries to the foot and ankle for which shoes could have been a contributing factor.

To further control, I focused on the eight metatarsal fractures that occurred and the 187 instances of ankle sprain. The ankle sprain number is consistent with the incidence rate reported by an Australian study,⁵ even though that study was based on recreational players (3.85 per 1000 for the study, 4.1 per 1000 in this season for the NBA).

I attempted to match each of the NBA injuries with a shoe. However, changes in color combinations make it difficult if not impossible to completely control for this. There are 125 instances in which there is a high degree of confidence that a specific shoe was worn at the time of a specific injury. These were identified using pictures and video, as well as the SLAMOnline shoe database.

Broadly speaking, there doesn't appear to be one particular shoe or brand that stands out as a problem. Injuries seem to be in line with the overall percentage of shoe wearers. (That is, injuries seem to occur at the same rate regardless of shoe brand.) And, because of the wide range of shoe brands, models, and types, it's difficult to draw any more specific conclusions.

function like crap!" said Bruce Williams, DPM, director of gait analysis studies for the Weil Foot & Ankle Institute in the greater Chicago area. "I will say that I have seen improvements in function over the last ten years in most shoes in most sports. That said, it does not appear that the injury rate has decreased. While I think shoes can definitely make things worse, there is an even bigger issue with team sports medical professionals not knowing how to evaluate and screen the foot properly to minimize the most common risks for a season-ending injury like fifth metatarsal fracture."

Surprisingly, there are only five footwear manufacturers that have more than five NBA wearers. Those are Nike, Adidas, Nike's Jordan Brand, Underarmour, and relative newcomer Peak, a Chinese brand more known for its Li-Ning brand. There are 13 other companies, including well-known brands like Reebok, Spalding, and New Balance that have five or fewer players (and in most cases, only one) that wears this brand.

While officials from Nike and Adidas declined to speak on the record or to make available the terms or lists of their athletes, it's

relatively easy to determine which players are wearing which shoes. What's more difficult to assess is how players wear the shoes. NBA players can go through several pair of shoes in a game—sometimes based on comfort and feel, but more often than not, on habit and superstition. Some players elect to change shoes at almost any opportunity, ignoring most principles of break-in and alleging the stiffness and out-of-the-box "freshness" of the shoe puts it at the most pure state.

David Craig, LAT, ATC, the long-time athletic trainer for the Indiana Pacers and currently a consultant for St. Vincent Sports Performance in Indianapolis, agreed with this conclusion. In his experience, shoe choice tended to be handled almost entirely by the players, and the team medical staff would just have to keep up.

"Some players would have boxes of shoes—the same, different—inside their lockers or stored somewhere. [The player] was responsible for how they broke them in unless we had customized it somehow for him with pads, orthotics, or cushions. At that point, we got more involved because we had to adjust to the player. If he changed shoes every game, we had to change along with him," Craig explained.

What is surprising is that, with these shoes, there is little in the way of personalization or customization, particularly in terms of fit. There's a widely-held belief that endorsement deals lead to shoes that are custom designed for an athlete's feet. Instead, the customization is more general. Representatives from both Adidas and Nike told me a shoe is not made for or based on an athlete's foot, but is guided by the athlete's preferences.

"Some players like more support. Some like more cushion," said Leo Chang, lead designer for Beaverton, OR-based Nike. "It's more like a guide than a full custom. There's no custom last or mold for an individual athlete once we get beyond a prototype stage."

That said, some aspects of Kevin Durant's signature Nike shoes were revisited after the Golden State Warriors' small forward sustained a Jones fracture in October 2014, when he was playing for Oklahoma City.

"In most players, you'll see the heel flare up first on a pressure map, then the forefoot, and then the toe. Durant actually has a lot of pressure in the midfoot, where he had the metatarsal Jones fracture," Chang said. "We shifted the silhouette of the outsole so that it accounts for that. A lot of running shoes will sculpt away on the outer side of the midfoot, but if you sculpt away from there, you're not giving him enough cushioning or support. We shifted that to the lateral side to help give him more cushioning."

The players themselves seem to focus on looks as much as performance. When Durant wanted Flywire (a stretchy, socklike fabric embedded with structural filaments for support) added to his shoe, it was because of the look and its inclusion on Kobe Bryant's shoe, not the performance aspects.

"When [Flywire] first jumped on the scene," Durant told NiceKicks.com while discussing his new shoe,² "I was telling my guys, 'Man, I would love to have that on my shoe.' It looked so nice, first of all, but I didn't know how it played. To see Kobe in it, I was a little jealous."

In most cases, athletes work with designers on the shoe concept within predetermined functional parameters, and the resulting design is then adapted for mass manufacturing. The customization process is more like adding options to a car than designing the car itself.

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For lower extremity practitioners who work with basketball players at less-elite levels, it may be reassuring to know that even NBA stars with huge endorsement deals sometimes have difficulty reconciling fashion-forward preferences with fit and performance.

"If you love the Air system [pressurized air cells in the midsole, and you love where the KD6 Elite [his previous model] was, but you didn't like the way it was a little slappier, didn't bend, and was a little clunkier, those are the things that KD himself experienced," Chang said. "On [Durant's] previous model, he loved that Zoom sensation [more air cushioning in the heel, less in the forefoot], but he just said it felt like he was swimming in mud a little bit, because it was way too stiff and clunky. That's something I learned a ton from, and I said, 'Ok, I love that you hated it. I can make that better for you.' We tried to do that."

Aside from anecdotal reports, such as a 2013 article suggesting a run of NBA injuries in Adidas endorsers,³ there is little to suggest any one shoe model or manufacturer is associated with a higher or lower injury risk. The anecdotal information tends to be based around pattern recognition more than true causal relationships.

An injury database analysis conducted in conjunction with this article also found no evidence that injury incidence in the NBA is associated with shoe brand or design (see sidebar). This parity is predictable. Although each shoe manufacturer has its own technology or methodology, the technological underpinnings of the shoes are relatively similar. Shoe stiffness, construction, friction, and cushioning tend to vary in subtle ways that seem to be based more on comfort and preference than performance.

The medical literature is similarly inconclusive about footwear and injury risk in basketball. In a 2008 study of college basketball players published in the *Journal of Athletic Training*,⁴ researchers found no difference in ankle sprain rates between shoes with a cushioned column system in the heel and shoes with a traditional heel counter.

A 2013 Australian study of recreational basketball players found ankle injuries were 4.3 times more likely to occur in players wearing shoes with air cells in the heel than those wearing shoes without air cells.⁵ The authors suggested, however, that recreational players wear their expensive shoes for too long, using them after the cushion,

stability, and grip is compromised. In addition, the Australians noted very few of the players in their study—even those with a history of ankle injury—used tape or ankle braces, which could have affected injury rates.

These two factors are obviously not the case in the NBA, though again, replacement of shoes is inconsistent and there is also no requirement for bracing with most teams, though most players do use tape or fitted braces regularly.

Both the Nike and Adidas representatives I spoke with suggested another variable that's entirely reliant on the player: lacing. Perhaps, because of the emphasis on comfort, many NBA players tend to lace their shoes loosely, which can compromise both the fit and the support. The actual structural rigidity, support, and fit will change each time the shoes are laced, and may differ significantly from the designers' intentions. There is no consistency.

"Ideally, there would be a consistent and custom tension for each player, like we see with tennis rackets," said the Nike staffer. "That's impossible, or at least impractical, so we tend to design for a range, giving a minimum stiffness at a minimum tension."


Nike in particular is conscious of this issue and has recently shifted away from laces on some of its shoe styles in favor of supportive stretch fabrics.

Several NBA staffers pointed out that NBA feet are, almost by definition, larger than those of the general population. While NBA players' shoe sizes range from a relatively normal 10.5 to an astounding 20 (Brook Lopez), most teams' average shoe size is in a very tight range between 14 and 15. Scaling shoe designs to accommodate these larger feet is typically not an issue, experts said, and the modern use of lightweight materials has limited the extent

to which a larger shoe is necessarily a heavier shoe. But design efforts to minimize shoe weight also run the risk of limiting the shoe's ability to withstand the repetitive loading associated with basketball,⁶⁻⁹ especially in larger players.

The area that appears most ripe for study is friction, or "stick." A 2014 study from China suggests that, as the shoe-surface interface in basketball has evolved to allow for quicker acceleration and harder stops, the in-shoe shear stresses generated during cutting as a result could be problematic.¹⁰ Basketball could benefit from additional research on factors affecting shoe-surface interface, which has been more plentifully studied in football (American and European).

Another interesting possibility is that shoe design may not make a difference, or that the seeming parity between shoe models and manufacturers means that shoes are a neutral in the causation of injuries. The focus on comfort over performance lends to this theory, which seems consistent with that proposed by University of Calgary biomechanist Benno Nigg, PhD, in relation to running shoes and injury risk.¹¹

Even if, on balance, footwear choices based on fashion and personal preference do not appear to have affected injury rates in basketball players, opportunities still exist for lower extremity practitioners to improve fit and function in players of all levels by matching each athlete with the most appropriate shoe. Determining that best match, however, is a complex challenge—and hopefully one that will be the focus of future research. 

Will Carroll is a writer in Indianapolis who specializes in covering injuries in professional sports.

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Jump mechanics and risk of patellar tendinopathy

To understand the association between jumping biomechanics and transmission of forces through the patellar tendon, practitioners must have a working knowledge of the anatomy of the knee, as well as the biomechanical factors that determine force transmission through the knee.

By Rob Halle, PT, DPT, OCS, CSCS

Patellar tendinopathy (PT), or “jumper’s knee,” is a cause of knee pain that ultimately results in impaired healing of the tendon and a breakdown of the tendon’s key function: its load-absorbing and transmitting properties.^{1,2} PT is most common in athletes, particularly those who engage in sports that demand explosive, powerful movements such as jumping.³⁻⁵ Among sports, PT is most common in volleyball and basketball, with a prevalence rate in elite volleyball and basketball players of 45% and 32%, respectively; overall prevalence in elite athletes is 14.2%.⁵ Prevalence among nonelite volleyball players is reported to be 14.4%, with overall prevalence of 8.5% among nonelite athletes.⁶ PT not only causes pain, which limits the function of the affected tendons, but can also be associated with a loss in performance and ability to participate in sporting activities. Kettunen et al⁷ reported 53% of athletes suffering from PT had ended their athletic careers due to the condition at a 15-year follow-up.

Despite the prevalence and potential negative repercussions, the etiology of this condition remains largely unknown.³ Possible risk factors include age, gender, body mass index, leg-length difference, arch height, hamstring flexibility, ankle dorsiflexion range of motion, playing surface, amount of training, and stronger quadriceps. The primary risk factors, however, may be related to the biomechanics of jumping and landing from a jump.^{8,9} Improper landing technique may increase tendon strain and the transmission of forces through the patellar tendon, thereby increasing the likelihood of developing PT.⁹⁻¹¹ To understand the association between jumping biomechanics and transmission of forces through the patellar tendon, one must have a working knowledge of the anatomy of the knee, as well as the biomechanical factors that determine force transmission through the knee.

Knee extensor mechanism

The patellofemoral articulation and associated musculotendinous structures are often referred to as the extensor mechanism of the

Improper landing technique may increase tendon strain and transmission of forces through the patellar tendon, increasing the likelihood of developing tendinopathy.

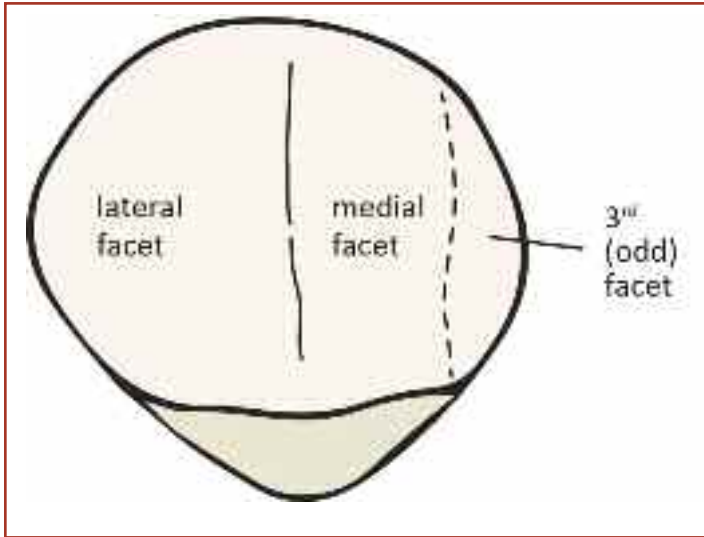


Figure 1. The three articular facets of the patella.

knee. Although this motor unit does provide concentric extension of the knee, it also works eccentrically during the gait cycle and activities like jumping and squatting.¹²

The patella, the largest sesamoid bone in the body, features insertions from the quadriceps muscles proximally and the patellar tendon distally. The superficial surface of the patella is concave, and its articular surface contains three facets (Figure 1) and a vertical central ridge. The lateral facet is broad and is separated from the smaller medial facet and the more medial odd facet by the vertical central ridge. The patella articulates with the anterior articular surface of the distal femur at the femoral sulcus. The lateral articular surface of the femur matches the patella and is broader than the smaller medial articular surface of the femur.^{12,13}

The proximal insertion of the patellar tendon is the inferior pole of the patella, and the distal insertion of the patellar tendon is the tibial tubercle. The tendon transmits force produced by the quadriceps across the knee joint to its insertion on the tibia, thereby generating an extension torque. The transmission of forces and cumulative load placed on the patellar tendon throughout active knee extension is influenced by the patella and its effect on quadriceps function. The mechanical efficiency of the quadriceps is greatly improved by the patella because it enables the patellar tendon to lengthen the moment arm of the quadriceps. The patella therefore functions as an anatomic pulley, deflecting the line of quadriceps action away from the joint. This pulley action increases the angle of pull and the ability of the quadriceps to generate an extension torque.¹⁴ The loss of the patella has been shown to decrease torque of

the quadriceps by 49% (Figure 2).¹⁴ By dividing torque or moment of the quadriceps by the moment arm, it is possible to calculate the force acting on the patellar tendon.^{9,15} Although mechanical loading is essential for the health and performance of tendons, the magnitude and characteristics of optimal loading are still largely unknown, and overloading the patellar tendon has been shown to increase the risk of an athlete developing PT.¹⁵

Landing biomechanics

As mentioned previously, PT is most common in the volleyball and basketball populations, in which jumping is a key aspect of performance. In addition to transmitting force from the quadriceps to create extension, the patellar tendon aids the other joints of the lower limb in dissipating the kinetic energy generated when landing from a jump.^{9,16}

A 2006 cross-sectional study evaluated performance measures in 113 male and female volleyball players, along with their flexibility and strength.¹⁶ Outcome measures included sit and reach flexibility, dorsiflexion range of motion, jump height, and ankle plantar flexor strength. Ultrasound imaging of the tendon was also performed.

Approximately 25% of the individuals had hyperechoic and thickened proximal portions of their patellar tendons, known precursors of PT. Of the outcome measures assessed in this study, loss of dorsiflexion range of motion was the only metric associated with PT. Athletes with less than 45° of ankle dorsiflexion were 1.8 to 2.8 times more likely to have abnormal findings on imaging of the patellar tendon than those with more than 45° of dorsiflexion. This may be due to the role the ankle joint plays in the absorption of landing forces. During landing from a jump, the forefoot contacts the ground and the ankle moves into dorsiflexion. This is coupled with eccentric activation of the calf muscles and is responsible for absorbing approximately 37% of the total kinetic energy produced when landing

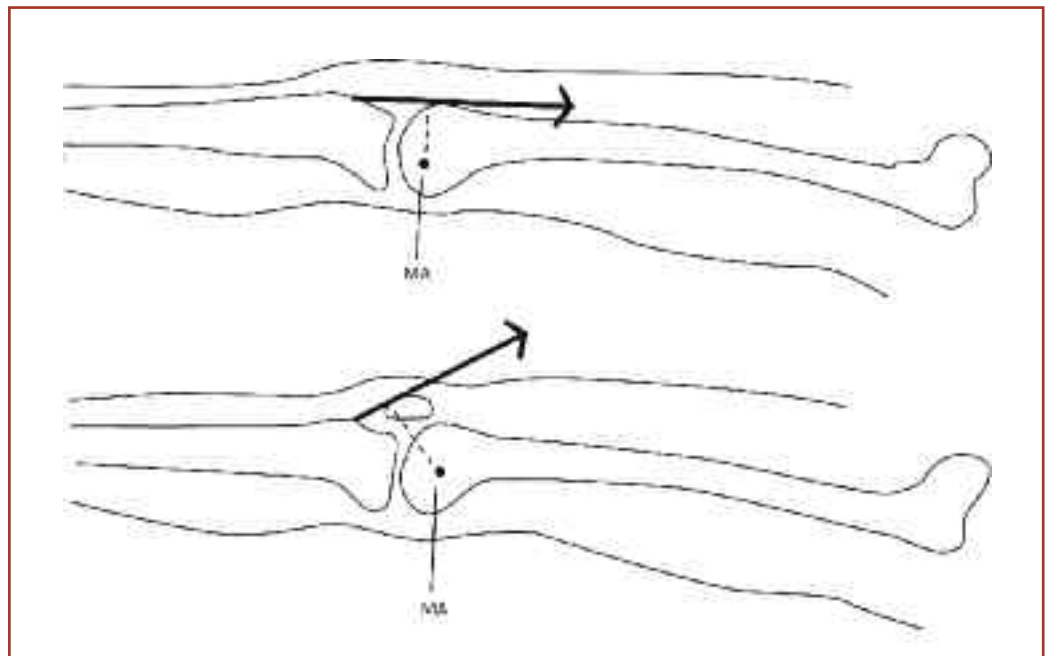


Figure 2: This figure demonstrates the changed action line of the quadriceps (arrow) and the decreased moment arm that results from the removal of the patella (dotted line). MA = moment arm.

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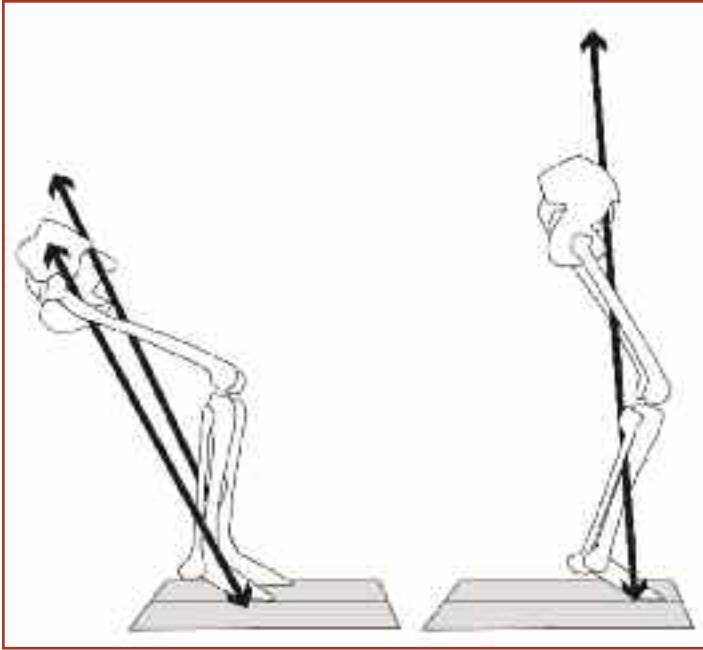


Figure 3: Depiction of lower limb alignment at time of peak patellar tendon load during the horizontal (left) and vertical (right) landing phases of the stop-jump task.

from a jump.^{16,17} A decrease in ankle dorsiflexion that alters this biomechanical pattern may increase load at the patellar tendon during jumping activities and, in turn, increase the risk of PT or other patellar tendon injury.¹⁶

To further elucidate the understanding of joint kinematics and their effects on patellar tendon loads, Edwards and colleagues performed a study comparing two phases of a stop-jump landing task.¹⁸ The two phases of the landing task were the horizontal phase and the vertical phase. Each participant was asked to accelerate forward for four steps toward two force plates, stop, and perform a symmetrical two-foot landing on the force plates; this described the horizontal phase. Immediately after landing, the participant would jump vertically, strike a ball that was suspended from the ceiling, and perform a symmetrical two-foot landing on the force plates; this described the vertical phase. The authors used motion-capture cameras, light-emitting diodes placed on the skin, and force plates to measure joint kinetics and kinematics for the two landing phases.

Horizontal jump landing, which is common in sports such as volleyball and basketball, was associated with a significantly higher mean patellar tendon load (force), a higher patellar tendon loading rate, a higher mean knee joint moment, greater hip flexion at initial contact, and a faster time to reach maximum patellar tendon force compared with vertical jump landing (Figure 3).

Edwards et al¹⁸ speculated that decreased dorsiflexion range of motion and landing with greater knee and hip flexion may lead to increased patellar tendon load (force) experienced during the horizontal landing phase. Joint kinematic data revealed that, during the vertical jump landing, participants also landed with significantly greater plantar flexion at initial contact and proceeded to move into greater dorsiflexion range of motion at the time of maximum patellar load compared with the horizontal landing phase. During horizontal landing, participants' dorsiflexion range of motion remained virtually unchanged from time of initial contact to time of maximum patellar tendon load. During the horizontal landing phase, participants also

landed with significantly greater knee and hip flexion at initial contact relative to the vertical landing phase.¹⁸ These results suggest the horizontal phase of the stop-jump movement places the highest load on the patellar tendon, potentially leading to the development of patellar tendinopathy.

Systematic review

A systematic review investigating the relationship between jumping mechanics and PT was performed in 2014.¹⁹ It included six cross-sectional studies due to the lack of prospective studies at the time of the review. Several of the studies compared participants with active PT with controls, while others compared controls with participants who had either experienced PT in the past or who were asymptomatic with patellar tendon abnormalities on imaging. In those who had active PT and those with a history of PT, kinematics did not differ significantly from controls.

The authors did note small, albeit statistically insignificant,



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differences in several areas. Compared with controls, participants with active PT demonstrated smaller maximum ankle dorsiflexion range of motion, a smaller maximum angular acceleration of the hip, and a larger maximum knee flexion angle during landing. Participants with active PT also displayed less angular velocity of the knee than controls during the eccentric portion of jump takeoff. Individuals with a history of PT exhibited smaller plantar flexion angles at initial contact than controls. During landing, they also demonstrated a smaller change in knee range of motion from initial contact to peak vertical ground reaction force, less knee flexion at the time of peak vertical ground reaction force, and a greater eccentric angular velocity of the knee.

Because patellar tendon abnormality is thought to be a precursor to tendinopathy, it has been said that individuals with such abnormalities have jump biomechanics that may lead to the development of PT.^{11,19} Most differences between the tendon abnormality group and controls existed during the horizontal landing phase. At initial contact, more hip and knee flexion were noted in those with tendon abnormalities than in controls, along with higher hip and knee extension velocities. At the time of peak patellar tendon load, they also had more knee angular velocity, more hip adduction, and greater hip external rotation velocity. These results suggest that patellar tendon abnormality is associated with higher angular velocities and a less upright position during landing. The larger hip and knee flexion angles at landing limit the available range of motion and decrease the displacement of the center of mass after touchdown. This increased stiffness of the landing can increase loading rates and peak patellar tendon forces.¹⁹

Prospective findings

Despite the existence of a relevant systematic review, it is difficult to draw strong conclusions from these data, partially because of the studies' cross-sectional design. The first prospective cohort to examine the relationship between stiff landing mechanics and the development of PT was published in 2016.⁸ The 49 study participants (17 women) included the members of three basketball teams, two volleyball teams, and one korfbal team. A landing error scoring system (LESS) jump test was performed at the start of the sports season, as was 3D motion analysis measuring kinetics and kinematics of jumping and landing. The horizontal phase of the LESS was performed with the player jumping from a 30-cm high box onto two force plates used to measure ground reaction forces. Each force plate was placed in front of the box at a distance half the participant's height. Participants were instructed to land with both feet, one on each plate, and immediately perform a maximal vertical jump. Participants were followed over the course of one to two athletic seasons.

Of the 49 athletes who participated in the study, only three developed PT, an annual incidence of only 4.5%. Two of the three exhibited less range of motion in the lower extremity joints at baseline than controls, but not for all joints. One had a large hip flexion angle at initial contact, which limited the available range of motion change toward flexion and resulted in a stiffer landing than in the uninjured athletes. Another player who developed PT had a large dorsiflexion angle at initial contact and a heel-first landing, which also limited the amount of joint range of motion change available to absorb excessive impact forces. The kinematics of the third athlete who developed PT did not differ significantly from those of the uninjured athletes.⁸

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Since no common knee, ankle, or hip kinematic patterns could be identified in the three individuals who developed PT, these data suggest there may be more than one altered landing pattern associated with a high risk for PT. The commonality among the patterns in question in this study is that they demonstrated a decreased joint range of motion excursion resulting in a stiff landing, which is often associated with PT.^{8,16,18}

Conclusion

Many risk factors have been identified for the development of patellar tendinopathy, including age, gender, training frequency, quadriceps strength, arch height, and leg-length difference.^{8,20} It has also been hypothesized that altered biomechanics and kinematics of landing may play a role in the development of PT. Several cross-sectional studies have demonstrated that kinematic differences and alterations exist in a population of individuals with patellar tendinopathy, abnormal patellar tendon imaging, or a history of PT. The majority of this research suggests that a limited excursion of joint range of motion from initial contact to the time of peak force on the patellar tendon contributes at least in part to any increased risk of PT associated with jump landing.^{8,9,11,17,19} It has also been pointed out that sport-specific horizontal type jump-landing techniques may be associated with a higher risk of developing PT than vertical jump-landing techniques.^{10,11,19} There is also some evidence to suggest athletes with increased lower extremity stiffness during landing may be at increased risk for developing PT.

Because much of this research is cross-sectional and does not lend itself to strong conclusions, additional research on associations between PT and jump landing in large prospective cohorts is


needed. Even if such a relationship exists, it is also plausible that jump-landing biomechanics play only a small role in the big-picture etiology of PT. As noted previously, the onset of PT is often multifactorial, with intrinsic and extrinsic contributing factors. Current evidence suggests stiff landing mechanics combined with limited range of motion may play a part in development of patellar tendinopathy. Recognizing the multifaceted nature of the etiology of PT, treatment plans focusing on increasing dorsiflexion range of motion may aid in the prevention of this condition in the jumping athlete. Similarly, the development of strategies that emphasize joint excursion during landing, thus increasing landing time, may have comparable beneficial effects. Although more research is needed, the current body of knowledge may be useful in developing successful prevention strategies to guard against the development of patellar tendinopathy. 

Rob Halle, PT, DPT, OCS, CSCS, is a board-certified orthopedic physical therapist currently stationed at the United States Military Academy in West Point, NY, and a fellow in the US Army Baylor University Sports Physical Therapy Fellowship at West Point.

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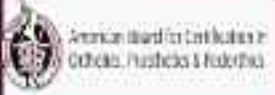
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Sigvaris offers a new generation of anti-embolism stockings to help prevent deep venous thrombosis and provide the benefits of graduated compression for patients transitioning from recovery to early rehabilitation. Available in calf-length and thigh-high styles, the stockings feature an open-toe design that allows for easy inspection of the feet. The anatomical foot design makes the stockings easy to wear with shoes. The anti-embolism stockings feature 18-23 mm Hg of graduated compression and a comfortable top band that stays in place. The unisex products are latex-free to prevent skin irritation.

Sigvaris
800/322-7744
sigvarisusa.com



SPIO Lower
Body Orthosis

The SPIO Lower Body Orthosis is designed to assist with gait and stability in pediatric patients with spastic diplegia, hypotonia, Down syndrome, ataxia, autism, and sensory processing disorder, as well as other diagnoses. The specially milled fabric is lightweight, wicking, antimicrobial, and breathable, and features high rebound and strong neutral memory to help promote proprioception and mid-line body alignment. The Lower Body Orthosis is often combined with the company's Thoracolumbar Spinal Orthosis or the Upper Body Orthosis. All SPIO products are made in the Seattle area.

SPIO
877/997-SPIO (7746)
spioworks.com



Tetra-Flex
Clip-Free Bandage

Tetra announces the Tetra-Flex CF (clip free) Woven Elastic Bandage. Tetra-Flex CF is a premium weave of Spandex and selected long-staple cotton providing maximum compression and durability, and its new self-closure system now makes it easy to apply and adjust. Up to this point, only the company's lighter-weight knit bandages offered the clip-free option. The durable bandage is designed to withstand repeat washings and applications. Available in non-sterile and sterile options in four standard widths (2", 3", 4", and 6") and a 5.5-yard stretched length and in special stretched lengths of 11 and 15 yards for selected widths.

Tetra Medical Supply Corp.
800/621-4041
tetramed.com



STS Trans-Tibial
Molding Sock

The STS Company has announced the addition of a new molding sock to its family of casting materials. The Trans-Tibial sock, developed as a part of a postoperative rigid dressing system introduced recently in Australia, is suited for obtaining a negative model of a below-knee amputated residual limb. The sock features a newly designed knit and a polyurethane resin incorporated into the sock that results in a firmer and stronger negative mold. The molding socks are donut rolled for easy application and will not shorten or deform the limb when applied. Available in a range of sizes.

STS Company
451/381-4602
stsox.com

Visit lermagazine.com/products for more products and to submit your new product listing.

ler new products



Support the Foot Quick Tape

New from Support the Foot is Quick Tape, a one-piece foot tape that offers a convenient alternative to low Dye taping. Clinicians can now ditch the scissors, adhesive spray, and different sizes of tape for one easy and efficient Quick Tape application. The tape has a thin, breathable, nonstretch adhesive design that custom fits to the shape of either foot. Quick Tape indications include bunions, low or high arches, flat feet, Achilles tendon pain, foot pronation, arthritis, neuromas, shin splints, plantar fasciitis, and navicular syndrome. The product is billable under CPT code 29540, with modifier 59 for bilateral.

Support the Foot
253/981-4849
supportthefoot.com



Abeo Biomechanical Footwear

Abeo biomechanical footwear promotes comfort, mobility, and overall health and wellness, along with classic footwear designs. Product lines include B.I.O.system (stands for built-in orthotics) sandals and shoes, AeroSystem athletic performance footwear, SmartSystem walking shoes developed at Stanford University to reduce knee pain, LiTe lightweight technology for freedom of motion and flexibility, the 24/7 collection for all-day comfort, and 3D orthotics customized to fit every unique foot and arch type. Abeo uses digital scanning technology to match each foot and arch type with footwear and orthoses.

Abeo
855/274-ABEO (2236)
abeofootwear.com



PDE Orthosis From Fabtech

Fabtech Systems offers the new PDE (posterior dynamic element) Orthosis, an advanced below-knee composite orthosis utilizing the PDE modular composite spring system for a range of orthotic applications including ankle and calf weakness. The orthosis facilitates postfitting adjustment and tuning to improve fluency and stability during gait and higher-level activities. Users may change the strut stiffness or ankle alignment for different activities; they can also adjust the device relative to the heel height of their shoe. Nine spring options are available for patients of various weights and activity levels.

Fabtech Systems
800/322-8324
fabtechsystems.com



Dr. Harvey's Herbal Motion

Dr. Harvey's Herbal Motion is a new cream developed by New York orthopedic surgeon Harvey Manes, MD, to help soothe aches and pains with all natural ingredients as an alternative to anti-inflammatory drugs and chemical-based creams. The formula includes capsaicin, aloe, arnica, boswella, and hemp oil to treat muscle, joint, and arthritic pain, including symptoms in the lower extremities; it contains no paraben, camphor, or phthalate. Herbal Motion helps to stimulate the affected area without the medicinal smell of other popular remedies. A 4-oz jar of Herbal Motion sells for \$19.95.

Herbal Motion
631/226-3380
herbalmotion.com

Viamet antifungal appears effective, safe

Research Triangle Park, NC-based Viamet Pharmaceuticals in January reported positive results from its Phase 2b randomized controlled trial of VT-1161 for onychomycosis of the large toenail. VT-1161 is a novel, once-weekly, oral antifungal drug.


The investigators assigned 259 patients to one of five study arms: 300 mg of VT-1161 once weekly for 12 weeks, then 12 weeks of placebo; 600 mg of VT-1161 once weekly for 12 weeks, followed by 12 weeks of placebo; either 300 or 600 mg of the antifungal agent once weekly for the full 24 weeks; or 24 weeks of once-per-week placebo.

At baseline, mean distal lateral subungual onychomycosis involvement of the large toenail was 46%; the average number of toenails affected was 4.6 across the trial arms.

The primary endpoint was complete cure at week 48, which required complete clinical cure and negative mycology. Patients were also evaluated for

complete cure at week 60.

In the intent-to-treat analysis, complete cure rates at 48 weeks were 0% in the placebo arm and 32% to 42% in the four VT-1161 arms, with all arms achieving statistical significance versus placebo. In the per protocol analysis, cure rates were as high as 55% in the VT-1161 groups. There was an 87% median reduction in the percentage of nail involvement at week 48 across the VT-1161 arms, compared with a 9% reduction in the placebo arm (all arms reached statistical significance vs placebo).


Complete cure rates continued to improve through week 60, and all active arms had a complete cure rate greater than 40% in the intent-to-treat analysis. No patient in any VT-1161 arm discontinued the study due to a laboratory abnormality, and fewer than 1% dropped out because of an adverse event. There was also no evidence of an adverse effect of VT-1161 on liver function. 

McGirt joins Össur's knee OA campaign

Foothill Ranch, CA-based Össur in February launched a public education campaign on knee osteoarthritis (OA) featuring professional golfer William McGirt.

McGirt, who is currently ranked 44th on the Official World Golf Ranking, has been wearing the company's Unloader One brace since 2013 and is being featured in various Össur ads and promotional activities. Get additional information on his ex-

perience and Össur's line of osteoarthritis knee bracing, along with other patient-centric content, at ossur.com.

In January Össur completed the integration of Bayreuth, Germany-based Medi Prosthetics (Össur acquired Medi last September). O&P customers in the US and Canada can learn more at ossur.com/mPro and can call 800/233-6263 with any questions. 

Birkenstock brings vegan sandals to US

Novato, CA-based Birkenstock USA in January introduced vegan footwear, previously available only in Europe, to US markets.

Several models of its sandals for adults and children, which are free from animal-based materials such as leather and wool, as well as dyes and

adhesives of animal origin, are available online at birkenstock.com/us/vegan and in select retail stores.

Last year PETA (People for the Ethical Treatment of Animals) Germany honored the company for its "compassionate" footwear. 

Apligraf alters genomics of chronic wounds


Science Translational Medicine on January 4 published randomized clinical trial results showing Organogenesis's bio-engineered living-cell wound-healing therapy demonstrated a significant change in the genomic profile of treated non-healing venous leg ulcers (VLU) compared with standard care.

The analysis from researchers at the University of Miami in Florida compared acute wound healing response in VLUs treated with the Canton, MA-based company's Apligraf plus compression therapy and VLUs treated with compression alone.

Investigators applied the therapies to VLUs equal to or

larger than 5 cm² in area that had undergone less than 40% area reduction after four weeks of treatment with compression therapy.

They biopsied the edge of the wounds before Apligraf application and one week after application.

Apligraf, Food and Drug Administration-approved for treatment of VLUs and chronic diabetic foot ulcers, modulated inflammatory and growth factor signaling and activated keratinocytes at the wound edge, successfully shifting the wound microenvironment from that of a chronic nonhealing ulcer to a healing milieu resembling that of an acute healing wound. 


Hanger prosthetist teaches AFO design

A prosthetist from Austin, TX-based Hanger in January volunteered his knowledge to a Missouri middle school project that had students designing cardboard and foam ankle brace prototypes that could be used by patients with spastic hemiplegia.

Hanger's Jeremy Burleson, BOCP, CPed, provided design perspective, demonstrated examples of professionally made orthoses, and evaluated the work

of more than 80 seventh graders at Truman Middle School in St. Joseph, MO.

Project Lead the Way (PLTW) sponsored the effort, aimed at introducing kids to engineering principles. The Indianapolis, IN-based nonprofit's broad mission is to provide transformative learning experiences for children in grades K-12.


Get more information on PLTW at pltw.org. 

ACFAS installs 2017 officers and board

The Chicago-based American College of Foot and Ankle Surgeons (ACFAS) in February installed its 2017-2018 officers and board of directors during the national surgical society's 75th Annual Scientific Conference in Las Vegas.

Laurence G. Rubin, DPM, FACFAS, of Mechanicsville, VA, is the organization's 66th president; John S. Steinberg, DPM, FACFAS, of Washington, DC, is president elect; Christopher L. Reeves, DPM, MS, FACFAS, of Orlando, FL, is secretary-trea-

surer; and Sean T. Grambart, DPM, FACFAS, of Champaign, IL, is immediate past president.

Directors are Michael J. Cornelison, DPM, FACFAS, of Cupertino, CA; Thanh L. Dinh, DPM, FACFAS, of Boston, MA; Meagan M. Jennings, DPM, FACFAS, of Mountain View, CA; Scott C. Nelson, DPM, FACFAS, of Omaha, NE; Aksone M. Nouvong, DPM, FACFAS, of Pomona, CA; Eric G. Walter, DPM, FACFAS, of Bronx, NY; and Randal L. Wraalstad, DPM, FACFAS, of Twin Falls, ID. 


Continued on page 62

GE Healthcare, NBA call for proposals

Chicago-based GE Healthcare and the National Basketball Association (NBA) in January announced four newly selected research initiatives and issued a call for a third round of research proposals focused on bone stress injuries for the organizations' Orthopedics and Sports Medicine Collaboration.

The latest round of winning research proposals that address myotendinous injuries went to Suzi Edwards, PhD, University of Newcastle, Australia, for the "HAMI study: investigating hamstring and adductor myotendinous injury risk factors in basketball;" Johannes Tol, MD, Academic Medical Centre, University of Amsterdam, the Nether-

lands, for the "Basketball and muscle injury (BAMI) study;" Bryan Heiderscheidt, PT, PhD, University of Wisconsin-Madison, for "Clinical, biomechanical, and novel imaging biomarkers of hamstring strain injury potential in elite athletes;" and Timothy Hewett, PhD, Mayo Clinic in Rochester and Minneapolis, MN, for "Comparative effectiveness of hamstring muscle strain injury prevention programs."


Up to \$1.5 million is available for proposals selected during the current round of funding, for which applications are due by April 17. For more information visit gex.brightidea.com/GENBACFP. 

OPAF announces 2017 board, sponsor

The Charlotte, NC-based Orthotic & Prosthetic Activities Foundation (OPAF) in January welcomed two new board members for fiscal year 2017.

The new members are JoAnne Kanas, CPO, DPT, national director for orthotics and prosthetics for Shriners Hospital for Children in Tampa, FL; and Vibhor Agrawal, PhD, ATP, assistant professor of physical therapy at the University of Miami Miller School of Medicine in Miami.

OPAF's 2017 officers are Sue Borondy, president, director of marketing and communications at Endolite; Karen Henry, vice president, president of KH Edits; and Nikki Hooks, CO, a board eligible prosthetist with Ability Prosthetics & Orthotics.

OPAF also announced in January that Össur Americas is a platinum sponsor for its 2017 First Clinics. The foundation's 2017 First Clinics schedule is available at opafonline.org. 


NYSPMA draws 2K for podiatric event

Two members of the New York State Podiatric Medical Association (NYSPMA) Foundation were recognized in January for outstanding achievements at NY17, the group's Podiatric Clinical Conference and Exhibition.

NYSPMA Vice President Paul Liswood, DPM, received the American Podiatric Medical Association's Meritorious Service Award for his role in advocating for New York State podiatric scope of practice, extending the message about podiatry's critical role in preventive care, and his numerous research-based pre-

sentations on the significant healthcare cost reductions associated with using a foot and ankle specialist.

NYSPMA President William Pierce, DPM, was recognized by the California School of Podiatric Medicine at Samuel Merritt University for his accomplishments as a past graduate of the program.


More than 2000 podiatrists, physicians, podiatric assistants, professors, students, residents, and exhibitors from across the country and internationally gathered for the event. 

AOPA celebrates its 100th anniversary

The Washington, DC-based American Orthotic & Prosthetic Association (AOPA) in February unveiled a commemorative website, AOPA100.org, as part of the association's yearlong celebration of its 100th anniversary. The website features AOPA's history, an interactive timeline, photo gallery, personal stories from AOPA members, and AOPA's plans for the future.

AOPA also reported in January that its clinical content committee for the organization's 2017 world congress will select the top 10 clinical education submissions for publication in a

special edition of the *Journal of NeuroEngineering and Rehabilitation*. Authors will also give a podium presentation of their paper and get special recognition at the upcoming congress, scheduled for September 6-9 in Las Vegas.


Other scheduled centennial activities include the release of a Who's Who 100th Anniversary Commemorative Membership Directory to distribute to members, events at the world congress, and sharing of weekly "Throwback Thursday" posts on the organization's Instagram, Twitter, and Facebook accounts. 

2020 global brace mkt estimated at \$4.3B

The global orthopedic brace market is expected to reach \$4.3 billion by 2020, at a CAGR (compound annual growth rate) of 5% from 2015 to 2020, according to data published in January by Frampton, UK-based BioPortfolio Reports.

The report segments the brace market into four categories: knee, foot and ankle, spine, and upper extremity. The knee brace segment had the

largest share of 42.5% of the market in 2014 and was valued at \$1.4 billion in the same year, which also saw the Asia Pacific market garner 14.1% of global brace sales, due to the region's low production costs. Rising awareness of braces among the general population is one factor contributing to the market increase, according to BioPortfolio.

Read the full report at bioportfolio.com. 

Avex raises \$7.6M for Footbeat launch

Grand Junction, CO-based Avex announced in January that it has secured \$7.6 million in Series A financing to fund its Q1 launch of Footbeat, an insole designed to increase circulation through cyclic pressure applied to the arch of the foot.

Orthopedic surgeon and


Avex cofounder David Mayer, MD, designed and developed Footbeat to address what he identified as common patient complaints about circulation enhancement devices, ie, immobility, noise, and discomfort.

Visit footbeat.com for more information. 

Bone Index device gets FDA clearance

Kupio, Finland-based Bone Index in January received 510(k) clearance from the US Food and Drug Administration for its second-generation point-of-care device for osteoporosis diagnosis.

The small handheld device uses ultrasound as alternative to dual-energy x-ray absorptiome-

try (DXA) bone densitometry to measure the tibia's cortical bone thickness and calculate bone mineral density at the hip. It connects to a laptop running Bindex software and detects osteoporosis with 90% sensitivity and specificity, according to a company release. 

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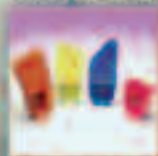


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