Are the claims made in orthopaedic print advertisements valid?

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Abstract

Purpose Advertisements are commonplace in orthopaedic journals and may influence the readership with claims of clinical and scientific fact. Since the last assessment of the claims made in orthopaedic print advertisements ten years ago, there have been legislative changes and media scrutiny which have shaped this practice. The purpose of this study is to re-evaluate these claims.

Methods Fifty claims from 50 advertisements were chosen randomly from six highly respected peer-reviewed orthopaedic journals (published July–December 2011). The evidence supporting each claim was assessed and validated by three orthopaedic surgeons. The assessors, blinded to product and company, rated the evidence and answered the following questions: Does the evidence as presented support the claim

made in the advertisement and what is the quality of that evidence? Is the claim supported by enough evidence to influence your own clinical practice?

Results Twenty-eight claims cited evidence from published literature, four from public presentations, 11 from manufacturer "data held on file" and seven had no supporting evidence. Only 12 claims were considered to have high-quality evidence and only 11 were considered well supported. A strong correlation was seen between the quality of evidence and strength of support (Spearman $r=0.945$, $p<0.0001$). The average ICC between the assessors' ratings was strong ($r=0.85$) giving validity to the results.

Conclusion Orthopaedic surgeons must remain sceptical about the claims made in print advertisements. High-quality evidence is required by orthopaedic surgeons to influence clinical practice and this evidence should be sought by manufacturers wishing to market a successful product.

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Introduction

Manufacturer advertisements are commonplace in orthopaedic journals and regularly present claims of clinical and scientific fact. There has long been a relationship between orthopaedic surgeons and the manufacturing industry which, although often mutually beneficial, has at times come under scrutiny with concerns over the neutrality of education and research [1, 2]. For manufacturers, print journal advertising remains a very successful vehicle to create product awareness in their target market [3, 4]. Orthopaedic surgeons, who must keep abreast of new developments, use various peer-reviewed and non-peer reviewed sources and must be able to validate the quality of the presented evidence [5].

The only previous assessment of the validity of claims made in orthopaedic print journal advertising was performed over a decade ago and assessed American publications only [6]. They found that approximately half of all the claims

assessed were poorly supported by scientific evidence, a result replicated in a recent similar study of claims made in otolaryngology print journal advertisements [6, 7]. Since this American study there have been legislative changes both in the United Kingdom and the United States in relation to medical device and pharmaceutical advertisement [8, 9]. There have also been high-profile episodes of medical device malfunction, including most notably metal-on-metal bearing arthroplasty [10]. These episodes have made orthopaedic surgeons more sceptical about new advances and they have been urged to scrutinise all available evidence before changing their clinical practice [11, 12].

The purpose of this study was to determine the validity of the claims made in print advertisements in orthopaedic print journals, published in both the United Kingdom and internationally, by determining the quality of their supporting evidence and their influence on the reader.

Materials and methods

Fifty claims of clinical or scientific fact were selected at random from print advertisements published between July 2011 and December 2011 appearing in: *The Journal of the American Academy of Orthopaedic Surgeons (AAOS)* (Journal Citation Reports 2011 impact factor (IF) 2.662), *The Journal of Bone and Joint Surgery (American Volume) (JBJS Am)* (IF 3.272), *The Journal of Bone and Joint Surgery (British Volume) (now the Bone and Joint Journal) (JBJS Br)* (IF 2.832), *Orthopedics* (IF 0.903), *The American Journal of Orthopedics (AJO)* (IF not listed), and *The American Journal of Sports Medicine (AJSM)* (IF 3.792) [13]. These journals were selected as they are well respected general orthopaedic publications with large readerships, international reach and contained print advertisements.

The advertisements were selected using a random number generator (Microsoft Office Excel 2007, Redmond, WA) and the first claim of scientific or clinical fact was identified from each advertisement. A statement of scientific and clinical fact was defined as any assertion about product performance that was relevant to patient care [6]. If no claim was made in the advertisement, or if the advertisement had already been assessed, then the next advertisement predicted by the random number generator was selected. This process was continued until 50 claims had been identified.

For each claim all the evidence referenced in the advertisement, as presented to the reader, was identified. This included any evidence located on the manufacturer's website, if the website address was referenced in the advertisement.

All the supporting evidence was collated and then edited (blinded) to remove any words which would identify the product or the manufacturer. The three assessors, who are all

practising orthopaedic surgeons working in different healthcare trusts within the United Kingdom and regular reviewers for peer-reviewed publications, were asked to assess each blinded advertising claim and the blinded referenced supporting evidence. To avoid confusion all claims were directly quoted from the advertisement and presented in the context intended by the manufacturer. The assessors were asked to contact the lead investigator if there was any ambiguity, but this did not happen.

The assessors reviewed the claims and the supporting evidence and were asked questions regarding the quality of the evidence presented and whether this would impact their clinical practice. The questions and possible answers are listed in Table 1.

The answers to each question for all 50 claims were entered for statistical analysis (IBM SPSS Statistics for Windows, Version 20.0., Armonk, NY) and the average interclass correlation coefficient between the assessors was calculated.

Results

Descriptive data

The distribution of journals from which the claims were randomly selected were *AAOS* eight (16 %), *AJO* seven (14 %), *AJSM* nine (18 %), *JBJS Br* 11 (22 %), *JBJS Am* nine (18 %), and *Orthopedics* six (12 %). A summary of the descriptive data relating to each claim can be found in Table 2. Most claims assessed related to adult reconstruction (42 %) or pharmaceuticals (30 %). The majority of advertisements referenced evidence to support the claim either

Table 1 Validity assessment questions and possible answers

Question 1. Does the evidence as presented support the claim made in the advertisement and what is the quality of that evidence?

Answer:

1. Yes, the evidence presented does support the claim made in the advertisement and the supporting evidence is of the quality expected of a respected peer reviewed journal. (High quality)
2. Yes, the evidence presented does support the claim made in the advertisement but the supporting evidence provided is not of sufficient quality expected by a respected peer reviewed journal. (Low quality)
3. No, the evidence presented does not support the claim made. (N.B. The respected peer-reviewed journal standard being *the Bone and Joint Journal* for which all the assessors are peer reviewers).

Question 2. Is the claim supported by enough evidence to influence your own clinical practice?

Answer:

1. Yes, the claim is well supported by evidence of sufficient quality that I would definitely consider incorporating into my clinical practice. (Well supported)
2. No, the claim is not supported by enough evidence to incorporate into my clinical practice. (Poorly supported)

Table 2 Summary of descriptive data

Description of claim	Number of claims (%)
Area of orthopaedics	
Adult reconstruction	21 (42 %)
Pharmaceuticals	15 (30 %)
Sports medicine	7 (14 %)
Surgical appliances	3 (6 %)
Trauma	2 (4 %)
Wound care	2 (4 %)
Referenced evidence to support claim	
Yes	43 (86 %)
No	7 (14 %)
Reference cited within print advertisement	
Yes	38 (76 %)
No	12 (24 %)
Referenced manufacturer's website (source of additional information)	
Yes	49 (98 %)
No	1 (2 %)
The academic status of best supporting evidence referenced	
Peer-reviewed publication (including registry data)	28 (56 %)
Presentation at a scientific forum	4 (8 %)
Data held on file at the manufacturer	11 (22 %)
No supporting evidence	7 (14 %)
(N.B. For the 17 (34 %) advertisements which cited more than one source of evidence to justify the claim made, all the referenced evidence was considered by the assessors)	
Type of study referenced	
Scientific	21 (31 %)
Clinical	47 (69 %)
Age of referenced study (from publication of advert)	
< 5 years old	35 (51 %)
5–10 years old	3 (19 %)
> 10 years old	9 (13 %)
Data held on file	11 (16 %)

through a citation on the advertisement (76 %) or by referencing the manufacturer's website which provided an additional source of evidence (98 %). The academic status of the best supporting evidence referenced to justify the claim made was a peer-reviewed publication (including registry data) in 28 claims (56 %), but in 18 claims no supporting evidence was referenced or the supporting data was held on file by the manufacturer. Most studies referenced were clinical and almost half (49 %) of the studies had no publication date or were published more than five years before the advertisement.

Analysis of the assessors' assessments

There was good inter-observer agreement between the assessors; the average interclass correlation coefficient for

question one (regarding the quality of evidence referenced) was 0.88, for question two (how well-supported the claim) it was 0.55, and for both answers combined it was 0.85. The strength of agreement can be considered as excellent, moderate, and excellent respectively [14, 15].

In relation to the quality of evidence presented to support the claims made and whether each claim was supported by enough evidence of sufficient quality to influence personal clinical practice, all three assessors agreed unanimously in 31 claims in each instance. A summary of the results can be found in Table 3.

A strong correlation was demonstrated between the quality of evidence and strength of support where two or more assessors agreed (Spearman $r=0.945$, $p<0.0001$).

When a claim was supported by published peer-reviewed evidence (including registry data) the assessors were more likely to consider the evidence high quality ($p<0.01$) and well supported ($p<0.01$) compared to the other supporting evidence presented, and the results remained significant even when the seven claims that referenced no supporting evidence were excluded ($p=0.02$ and $p=0.04$, respectively).

When comparing the advertising claims relating to medical devices and pharmaceuticals, pharmaceutical manufacturers were more likely to cite peer-reviewed evidence to reference their advertising claims but the difference was not significant ($p=0.13$). However, when two or more assessors agreed, they did find the pharmaceutical supporting evidence referenced higher quality ($p<0.01$) and better supported ($p<0.01$).

Table 3 Summary of assessors' results

Question 1. Does the evidence as presented support the claim made in the advertisement and what is the quality of that evidence?

Answer	Number of claims (%)
All assessors agree:	
Yes, high quality	9 (18%)
Yes, low quality	3 (6%)
No	19 (38%)
Two assessors agree:	
Yes, high quality	3 (6%)
Yes, low quality	9 (18%)
No	6 (12%)
All assessors disagree	1 (2%)

Question 2. Is the claim supported by enough evidence to influence your own clinical practice?

Answer	Number of claims (%)
All assessors agree:	
Well supported	2 (4%)
Poorly supported	29 (58%)
Two assessors agree:	
Well supported	9 (18%)
Poorly supported	10 (20%)

Discussion

Orthopaedic surgeons acquire knowledge from many sources and manufacturers' print advertisements are a readily available non peer-reviewed evidence source concerning the latest available products [5]. In the modern culture of evidence based practice and especially after recent high-profile medical device malfunctions, most notably with metal-on-metal bearing arthroplasty, orthopaedic surgeons should be cautious about novel treatments and have been urged to demand high-quality evidence to legitimise product claims [11, 12]. In this study we evaluated the validity of claims made in print journal advertisements published internationally, and the influence on the manufacturers' target audience: practising orthopaedic surgeons.

There was strong inter-assessor agreement which gave validity to the results. The agreement was greater for the first rather than the second question. We believe that the explanation for this is that the assessment of evidence quality against a standard peer-reviewed publication level is a less subjective test compared to the likelihood of a claim influencing personal clinical practice. It also suggests that the clinical practice of an orthopaedic surgeon is not purely influenced by the quality of evidence, but also driven by personal experience.

Overall the case for the validity of the claims made in orthopaedic print advertisements was weak; 38 (76 %) claims were considered by two or more assessors to have referenced low quality or no evidence to validate the claim made, and 39 (78 %) claims were considered to be supported by insufficient evidence to warrant incorporation into clinical practice. These results were similar to the previous assessment of orthopaedic print advertisement validity and it seems that the conclusion reached at that time, that orthopaedic surgeons should be

cautious about using statements from advertising claims to support their knowledge base, is still valid today [6].

Another similarity with the previous assessment is that if a claim referenced a published peer-reviewed source it was significantly more likely to be considered well supported by the assessors [6]. However, readers should still be cautious because 18 of the 28 claims (64 %) which referenced published peer-reviewed evidence were still considered poorly supported by two or more assessors. Often this was because the evidence referenced to support the claim was taken out of context and this is apparent when the individual claims were reviewed.

In one advertisement, which two assessors considered poorly supported, an adult reconstruction manufacturer claimed their hip system had "100 % survivorship at 16–19 years" which is not supported by evidence from the national joint registry data [16]. The advert referenced a publication in a well-respected peer-reviewed journal but when the article was scrutinised it was clear that the study population was small (38 total hip replacements [THR]), three THRs were lost to follow up, eight acetabular component revisions had been performed and that the 100 % survivorship was actually in relation to the femoral component alone [17].

This can be juxtaposed against another claim by a pharmaceutical company (where all three assessors agreed on the high-quality evidence and strength of support) that claimed their product could "treat the signs and symptoms of OA [osteoarthritis] of the knee". This claim referenced two randomised controlled trials published in respected peer-reviewed journals describing the product's efficacy in the clinical scenario presented. An example of five of the 50 claims assessed with a summary of their supporting evidence and the assessors' assessments can be found in Table 4.

Table 4 Supporting evidence and the assessors' assessments of the 50 claims

Generic product description	Claim (X, product name)	Study	Publication status	Brief evidence critique	Assessors' rating
Syndesmotic fixation device	"80 lb of force to reach 3 mm of displacement"	Scientific	DOF	Unpublished	Unanimous. Does not support claim
Prosthetic joint	"Restores joint kinematics"	Scientific	PRP	Published 1999. Cadaveric study of nine joints	Unanimous. Low quality evidence and poorly supported
Prosthetic joint	"Lowest relative risk of revision 2005, 2006, 2007, 2008, 2009 and 2010"	Clinical	PRP	Registry data 2005, 2006, 2007, 2008, 2009 and 2010	Two assessors; high quality and well supported One assessor; low quality and poorly supported
Rehabilitation device	"ACL patients recover faster with X"	Clinical	PRP	RCT 2011	Unanimous; high quality. Two assessors well supported one poorly supported
Analgesic	"Treat the signs and symptoms of OA of the knee(s) with X"	Clinical	PRP	Two RCTs 2004 and 2009	Unanimous. High quality and well supported

PRP peer-reviewed publication, DOF data on file, RCT randomised controlled trial

The relationship between the assessed quality of referenced evidence to justify an advertising claim and the likelihood of that claim impacting on the clinical practice of the reader cannot be understated. Each individual reviewer would only consider a claim to be well supported if they had first considered the evidence to be high quality (100 %).

The ramifications of this study are not just important for orthopaedic surgeons, but also for the manufacturing industry that spends vast amounts of money on marketing their products in an attempt to impact the clinical practice of the journals' readership [3]. It must be of concern then that of the 50 product claims assessed, the assessors would only consider incorporating 11 (22 %) into their clinical practice; this seems at odds with the high return on investment analysis, an average of \$5 return for every \$1 spent on advertising, as quoted in the literature for pharmaceutical manufacturers [3]. One lesson for industry from this study is the importance of high-quality evidence in influencing their target audience; this should motivate manufacturers into funding, performing and promoting research in order to generate better quality evidence. This is especially relevant for medical device manufacturers as the assessors felt that the quality and support of the evidence presented was weaker compared to pharmaceuticals.

The study does have limitations. The 50 claims randomly selected are obviously a small selection of all the orthopaedic print advertising. We only assessed the supporting evidence presented freely to the readership, either referenced on the advertisement or available on a referenced manufacturer website, so further evidence to justify the claim may exist. The rating system has not been formally validated, although to our knowledge no such tool exists, and we did demonstrate the reliability of our results through the strong inter-observer correlation between assessors. Comparison with the previous assessment is possible due to the similarity of method but there were differences in the design including the specific questions asked and the journals sampled [6]. It should also be noted that the standard of quality and support expected by the assessors is greater than would be expected to meet the relevant advertising regulation [8, 18].

In conclusion, we found that when practising orthopaedic surgeons validated the claims made in print journal advertisements the majority of supporting evidence referenced was weak and ultimately they were unlikely to consider using the manufacturers' product in their clinical practice. We urge orthopaedic surgeons to remain cautious about using advertisements as a source of evidence to influence their clinical practice and we would advise them to scrutinise all advertising claims. We also encourage manufacturers to continue to work with orthopaedic surgeons to produce products with a strong evidence base which could be universally accepted. Finally, it is incumbent upon the journals themselves

to request better quality evidence from manufacturers who submit advertisements with claims that have little support when further assessed.

Conflict of interest The authors declare that they have no conflict of interest.

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